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45 CFR Part 170

Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3; 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Part 495**

[CMS-3310-P]

RIN 0938-AS26

Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Proposed rule.

SUMMARY: This Stage 3 proposed rule would specify the meaningful use criteria that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet in order to qualify for Medicare and Medicaid electronic health record (EHR) incentive payments and avoid downward payment adjustments under Medicare for Stage 3 of the EHR Incentive Programs. It would continue to encourage electronic submission of clinical quality measure (CQM) data for all providers where feasible in 2017, propose to require the electronic submission of CQMs where feasible in 2018, and establish requirements to transition the program to a single stage for meaningful use. Finally, this Stage 3 proposed rule would also change the EHR reporting period so that all providers would report under a full calendar year timeline with a limited exception under the Medicaid EHR Incentive Program for providers demonstrating meaningful use for the first time. These changes together support our broader efforts to increase simplicity and flexibility in the program while driving interoperability and a focus on patient outcomes in the meaningful use program.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 29, 2015.

ADDRESSES: In commenting, please refer to file code CMS-3310-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following

address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3310-P, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3310-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Holland, (410) 786-1309, Medicare EHR Incentive Program and Medicare payment adjustment

Elisabeth Myers (CMS), (410) 786-4751, Medicare EHR Incentive Program
Thomas Romano (CMS), (410) 786-0465, Medicaid EHR Incentive Program

Ed Howard (CMS), (410) 786-6368, Medicare Advantage

Deborah Krauss (CMS), (410) 786-5264, clinical quality measures

Alesia Hovatter (CMS), (410) 786-6861, clinical quality measures
Elise Sweeney Anthony (ONC), (202) 475-2485, certification definition

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

Acronyms

API Application-Program Interface
ARRA American Recovery and Reinvestment Act of 2009
AAC Average Allowable Cost (of certified EHR Technology)
ACO Accountable Care Organization
AIU Adopt, Implement, Upgrade (certified EHR Technology)
CAH Critical Access Hospitals
CAHPS Consumer Assessment of Healthcare Providers and Systems
CCN CMS Certification Number
CDC Centers for Disease Control
CEHRT Certified Electronic Health Record Technology
CFR Code of Federal Regulations
CHIP Children's Health Insurance Program
CHIPRA Children's Health Insurance Program Reauthorization Act of 2009
CMS Centers for Medicare and Medicaid Services
CPOE Computerized Physician Order Entry
CQM Clinical Quality Measure
CY Calendar Year
EHR Electronic Health Record
EP Eligible Professional
EPO Exclusive Provider Organization
FACA Federal Advisory Committee Act
FFP Federal Financial Participation
FFY Federal Fiscal Year
FFS Fee-for-Service
FQHC Federally Qualified Health Center
FTE Full Time Equivalent
FY Fiscal Year
HEDIS Healthcare Effectiveness Data and Information Set
HHS Department of Health and Human Services
HIE Health Information Exchange

HIT Health Information Technology
 HITPC Health Information Technology Policy Committee
 HIPAA Health Insurance Portability and Accountability Act of 1996
 HITECH Health Information Technology for Economic and Clinical Health Act
 HMO Health Maintenance Organization
 HOS Health Outcomes Survey
 HPSA Health Professional Shortage Area
 HRSA Health Resources and Services Administration
 IAPD Implementation Advanced Planning Document
 ICR Information Collection Requirement
 IHS Indian Health Service
 IPA Independent Practice Association
 IPPS Inpatient Prospective Payment System
 IQR Inpatient Quality Reporting
 IT Information Technology
 MA Medicare Advantage
 MAC Medicare Administrative Contractor
 MCO Managed Care Organization
 MITA Medicaid Information Technology Architecture
 MMIS Medicaid Management Information Systems
 MSA Medical Savings Account
 MU Meaningful Use
 NAAC Net Average Allowable Cost (of certified EHR Technology)
 NCQA National Committee for Quality Assurance
 NCVHS National Committee on Vital and Health Statistics
 NPI National Provider Identifier
 NQF National Quality Forum
 ONC Office of the National Coordinator for Health Information Technology
 PAHP Prepaid Ambulatory Health Plan
 PAPD Planning Advanced Planning Document
 PFFS Private Fee-for-Service
 PHO Physician Hospital Organization
 PHS Public Health Service
 PHSA Public Health Service Act
 PIHP Prepaid Inpatient Health Plan
 POS Place of Service
 PPO Preferred Provider Organization
 PQRS Physician Quality Reporting System
 PHI Protected Health Information
 PSO Provider Sponsored Organization
 RHC Rural Health Clinic
 RPPO Regional Preferred Provider Organization
 SAMHSA Substance Abuse and Mental Health Services Administration
 SMHP State Medicaid Health Information Technology Plan
 TIN Tax Identification Number

I. Executive Summary and Background

A. Executive Summary

1. Purpose of Regulatory Action

a. Need for Regulatory Action

In this proposed rule, we specify the policies that would be applicable for Stage 3 of the Medicare and Medicaid EHR Incentive Programs. Under Stage 3, we are proposing a set of requirements that EPs, eligible hospitals, and CAHs must achieve in order to meet meaningful use, qualify for incentive

payments under the Medicare and Medicaid EHR Incentive Programs, and avoid downward payment adjustments under Medicare. These Stage 3 requirements focus on the advanced use of certified EHR technology (CEHRT) to promote health information exchange and improved outcomes for patients.

Stage 3 of meaningful use is expected to be the final stage and would incorporate portions of the prior stages into its requirements. In addition, following a proposed optional year in 2017, beginning in 2018 all providers would report on the same definition of meaningful use at the Stage 3 level regardless of their prior participation, moving all participants in the EHR Incentive Programs to a single stage of meaningful use in 2018. The incorporation of the requirements into one stage for all providers is intended to respond to stakeholder input regarding the complexity of the program, the success of certain measures which are part of the meaningful use program to date, and the need to set a long-term, sustainable foundation based on a consolidated set of key advanced use objectives for the Medicare and Medicaid EHR Incentive Programs.

In addition, we propose changes to the EHR reporting period, timelines, and structure of the Medicare and Medicaid EHR Incentive Programs. We believe these changes would provide a flexible, clear framework to reduce provider burden, streamline reporting, and ensure future sustainability of the Medicare and Medicaid EHR Incentive Programs. These changes together lay a foundation for our broader efforts to support interoperability and quality initiatives focused on improving patient outcomes.

b. Legal Authority for the Regulatory Action

The American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5) amended Titles XVIII and XIX of the Social Security Act (the Act) to authorize incentive payments to EPs, eligible hospitals, and CAHs, and Medicare Advantage (MA) organizations to promote the adoption and meaningful use of Certified Electronic Health Record Technology (CEHRT). Sections 1848(o), 1853(l) and (m), 1886(n), and 1814(l) of the Act provide the statutory basis for the Medicare incentive payments made to meaningful EHR users. These statutory provisions govern EPs, MA organizations (for certain qualifying EPs and hospitals that meaningfully use CEHRT), subsection (d) hospitals and critical access hospitals (CAHs), respectively. Sections 1848(a)(7), 1853(l) and (m),

1886(b)(3)(B), and 1814(l) of the Act also establish downward payment adjustments, beginning with calendar or fiscal year (FY) 2015, for EPs, MA organizations, subsection (d) hospitals, and CAHs that are not meaningful users of CEHRT for certain associated reporting periods. Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for Medicaid incentive payments. (There are no payment adjustments under Medicaid). (For a more detailed explanation of the statutory basis for the EHR incentive payments, see the July 28, 2010 Stage 1 final rule titled, “Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule” (75 FR 44316 through 44317)).

2. Summary of Major Provisions

a. Meaningful Use in 2017 and Subsequent Years

The Stage 1 final rule sets the foundation for the Medicare and Medicaid EHR Incentive Programs by establishing requirements for the electronic capture of clinical data, including providing patients with electronic copies of their health information. We outlined Stage 1 meaningful use criteria, and finalized core and menu objectives for EPs, eligible hospitals, and CAHs. (For a full discussion of Stage 1 of meaningful use, we refer readers to the Stage 1 final rule (75 FR 44313 through 44588).)

In the September 4, 2012 Stage 2 final rule (77 FR 53967 through 54162), we focused on the next step after the foundation of data capture in Stage 1, the exchange of that essential health data among health care providers and patients to improve care coordination. To this end, we maintained the same core-menu structure for several finalized Stage 1 core and menu objectives. We finalized that EPs must meet the measure for or qualify for an exclusion to 17 core objectives and 3 of 6 menu objectives. We finalized that eligible hospitals and CAHs must meet the measure or qualify for an exclusion to 16 core objectives and 3 of 6 menu objectives. We combined several Stage 1 measures included into Stage 2. With the experience providers gained from the Stage 1 final rule, we also increased functional objective measure thresholds in Stage 2 to increase efficiency, effectiveness, and flexibility. We also finalized a set of clinical quality measures (CQMs) for all providers participating in any stage of the program to report to CMS beginning in 2014. (For a full discussion of the meaningful use objectives and measures, and the CQMs we finalized under Stage 2, we refer

readers to the Stage 2 final rule at 77 FR 53967 through 54162.)

In this Stage 3 proposed rule, we build on the groundwork established in the Stage 1 and Stage 2 final rules, including continuing our goal started under Stage 2 to increase interoperable health data sharing among providers. In addition, this Stage 3 proposed rule would also focus on the advanced use of EHR technology to promote improved patient outcomes and health information exchange. We also propose to continue improving program efficiency, effectiveness, and flexibility by making changes to the Medicare and Medicaid EHR Incentive Programs that simplify reporting requirements and reduce program complexity. These changes proposed respond to comments received in earlier rulemaking that expressed confusion and concerns regarding increased reporting burden related to the number of program requirements, the multiple stages of program participation, and the timing of EHR reporting periods. In order to address these stakeholder concerns, one significant change we propose for Stage 3 includes establishing a single set of objectives and measures (tailored to EP or eligible hospital/CAH) to meet the definition of meaningful use. This new, streamlined definition of meaningful use proposed for Stage 3 would be optional for any provider who chooses to attest to these objectives and measures for an EHR reporting period in 2017; and would be required for all eligible providers—regardless of prior participation in the EHR Incentive Program—for an EHR reporting period in 2018 and subsequent years.

In addition to reducing program complexity, the Stage 3 proposed rule would further support efforts to align the EHR Incentive Programs with other CMS quality reporting programs that use certified EHR technology, such as the Hospital Inpatient Quality Reporting (IQR) and Physician Quality Reporting System (PQRS) programs, as well as continue alignment across care settings for providers demonstrating meaningful use. This alignment would both reduce provider burden associated with reporting on multiple CMS programs and enhance CMS operational efficiency. The Stage 3 proposed rule and ONC's 2015 Edition of Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications (hereinafter referenced as the "2015 Edition proposed rule") published elsewhere in this edition of the **Federal Register** would also continue to support

the privacy and security of patient health information within certified health IT.

b. Meaningful Use Requirements, Objectives and Measures for 2017 and Subsequent Years

Under this Stage 3 proposed rule, with the exception of Medicaid providers in their first year of demonstrating meaningful use as detailed in section II.F.1. of this proposed rule, all providers (EPs, eligible hospitals, and CAHs) would report on a calendar year EHR reporting period beginning in calendar year 2017. This proposal builds on efforts to align the EHR reporting period with reporting periods for other quality reporting programs identified in the Stage 2 final rule (77 FR 53971 through 53975 and 54049 through 54051) and the FY 2015 Hospital Inpatient Prospective Payment Systems (IPPS) final rule (79 FR 49854 through 50449). In addition, all providers, other than Medicaid EPs and eligible hospitals demonstrating meaningful use for the first time, would be required to attest based on a full year of data for a single set of meaningful use objectives and measures to demonstrate Stage 3 of meaningful use, which is proposed as optional for an EHR reporting period in 2017 and mandatory for an EHR reporting period in 2018, and subsequent years for all providers participating in the Medicare and Medicaid EHR Incentive Programs.

The methodology for the selection of the proposed Stage 3 objectives and measures for the Medicare and Medicaid EHR Incentive Programs included the following:

- Review attestation data for Stages 1 and 2 of meaningful use.
- Conduct listening sessions and interviews with providers, EHR system developers, regional extension centers, and health care provider associations.
- Review recommendations from government agencies and advisory committees focused on health care improvement, such as the Health Information Technology (HIT) Policy Committee, the National Quality Forum (NQF), and the Centers for Disease Control (CDC).

The information we gathered from these sources focused on analyzing measure performance, implementing discrete EHR functionalities and standards, and examining objectives and measures presenting the best opportunity to improve patient outcomes and enhance provider support.

Based on this analysis, we are proposing a set of 8 objectives with

associated measures designed to do all of the following:

- Align with national health care quality improvement efforts.
- Promote interoperability and health information exchange.
- Focus on the 3-part aim of reducing cost, improving access, and improving quality.

We intend to have this Stage 3 proposed rule be the last stage of the meaningful use framework, which leverages the structure identified in the Stage 1 and Stage 2 final rules, while simultaneously establishing a single set of objectives and measures designed to promote best practices and continued improvement in health outcomes in a sustainable manner. Measures in the Stage 1 and Stage 2 final rules that included paper-based workflows, chart abstraction, or other manual actions would be removed or transitioned to an electronic format utilizing EHR functionality for Stage 3. In addition, we are proposing the removal of "topped out" measures, or measures that are no longer useful in gauging performance, in order to reduce the reporting burden on providers for measures already achieving widespread adoption.

c. Clinical Quality Measurement

EPs, eligible hospitals, and CAHs must report CQMs in order to qualify for incentive payments under the Medicare and Medicaid EHR Incentive Programs and avoid downward payment adjustments under Medicare.

We are committed to continuing the electronic calculation and reporting of key clinical data through the use of CQMs. We are also focused on improving alignment of reporting requirements for CMS programs using EHR technology, maintaining flexibility with reporting requirements while streamlining reporting mechanisms for providers, and increasing quality data integrity.

This proposed rule addresses quality reporting alignment on several fronts. Our long-term vision seeks to have hospitals, clinicians, and other health care providers report through a single, aligned mechanism for multiple CMS programs. In the Stage 2 final rule, we outlined preliminary alignment options for quality reporting programs with the EHR Incentive Programs as the first step toward that vision (77 FR 54053).

In order to facilitate continuous quality improvement, we need a method to allow changes to meaningful use CQMs and the associated reporting requirements on an ongoing basis. For other CMS quality reporting programs, changes occur through the annual Medicare payment rules, such as the

Physician Fee Schedule (PFS) and the IPPS rules. Including CQMs in these annual rules would allow us to capture changes and updates annually. Therefore, we intend to further support alignment between the Medicare and Medicaid EHR Incentive Programs and other CMS quality reporting programs, such as PQRS and Hospital IQR, by including the reporting requirements for CQMs for providers demonstrating meaningful use in future rulemaking. We propose to continue encouraging CQM data submission through electronic submission for Medicare participants in 2017, and to require electronic submission of CQMs where feasible beginning in 2018 for Medicare providers demonstrating meaningful use. (We further discuss Medicaid CQM submission in section II.F.3. of this proposed rule.)

d. Payment Adjustments and Hardship Exceptions

The statute requires Medicare payment adjustment beginning in 2015. For the Stage 3 proposed rule, we propose to maintain all payment adjustment provisions for all EPs, eligible hospitals, and CAHs finalized in the Stage 2 final rule (77 FR 54093 through 54113 and 54115 through 54119) except for a change to the relationship between the EHR reporting period year and the payment adjustment year for CAHs. We are proposing a change to the timing of the EHR reporting period and related deadlines for attestations and hardship exceptions for CAHs in relation to the payment adjustment year, in order to accommodate a transition to EHR reporting for meaningful use on the

calendar instead of the fiscal year timeline. The payment adjustment provisions being maintained in the Stage 3 proposed rule include the process we finalized in Stage 2 by which a prior EHR reporting period determines a payment adjustment. We also maintain the four categories of exceptions based on all of the following:

- The lack of availability of internet access or barriers to obtain IT infrastructure.
- A time-limited exception for newly practicing EPs or new hospitals that would not otherwise be able to avoid payment adjustments.
- Unforeseen circumstances such as natural disasters that would be handled on a case-by-case basis.
- (EP only) exceptions due to a combination of clinical features limiting a provider's interaction with patients or, if the EP practices at multiple locations, lack of control over the availability of CEHRT at practice locations constituting 50 percent or more of their encounters.

e. Modifications to the Medicaid EHR Incentive Program

Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for the Medicaid EHR Incentive Program. For this Stage 3 proposed rule, we propose that under the proposed changes to EHR reporting periods that would begin in 2017, Medicaid EPs and eligible hospitals demonstrating meaningful use for the first time in the Medicaid EHR Incentive Program would be required to attest for an EHR reporting period of any continuous 90-day period in the calendar year for purposes of receiving an incentive, as well as avoiding the payment

adjustment under the Medicare Program.

We are proposing to continue to allow states to set up a CQM submission process that Medicaid EPs and eligible hospitals may use to report on CQMs for 2017 and subsequent years. We also propose amendments to state reporting on providers who are participating in the Medicaid EHR Incentive Program as well as state reporting on implementation and oversight activities.

f. Summary of Costs and Benefits

Upon finalization, the provisions in this proposed rule are anticipated to have an annual effect on the economy of \$100 million or more, making it an economically significant rule under the Executive Order and a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the final rule. The total federal cost of the Medicare and Medicaid EHR Incentive Programs between 2017 and 2020 is estimated to be \$3.7 billion in transfers. In this proposed rule we do not estimate total costs and benefits to the provider industry, but rather provide a possible per EP and per eligible hospital outlay for implementation and maintenance. Nonetheless, we believe there are substantial benefits that can be obtained by society (perhaps accruing to eligible hospitals and EPs), including cost reductions related to improvements in patient safety and patient outcomes and cost savings benefits through maximizing efficiencies in clinical and business processes facilitated by certified health IT.

TABLE 1—ESTIMATED EHR INCENTIVE PAYMENTS AND BENEFITS IMPACTS ON THE MEDICARE AND MEDICAID PROGRAMS OF THE HITECH EHR INCENTIVE PROGRAM
[Fiscal year—in billions]

Fiscal year	Medicare eligible		Medicaid eligible		Total
	Hospitals	Professionals	Hospitals	Professionals	
2017	\$1.6	\$0.3	\$0.4	\$0.8	\$3.1
2018	0.0	-0.2	0.1	0.5	0.4
2019	0.0	-0.2	0.0	0.3	0.1
2020	0.0	-0.1	0.0	0.2	0.1

B. Overview of the Regulatory History

The American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (ARRA) amended Titles XVIII and XIX of the Act to authorize incentive payments to EPs, eligible hospitals, and CAHs, and MA organizations to promote the adoption and meaningful use of CEHRT. In the July 28, 2010 **Federal**

Register (75 FR 44313 through 44588), we published a final rule (“Medicare and Medicaid Programs; Electronic Health Record Incentive Program”, or “Stage 1 final rule”) that specified the Stage 1 criteria EPs, eligible hospitals, and CAHs must meet in order to qualify for an incentive payment, calculation of the incentive payment amounts, and other program participation

requirements. For a full explanation of the amendments made by ARRA, see the Stage 1 final rule at 75 FR 44316. In that Stage 1 final rule, we also detailed that the Medicare and Medicaid EHR Incentive Program would consist of three different stages of meaningful use requirements.

In the September 4, 2012 **Federal Register** (77 FR 53967 through 54162),

we published a final rule (“Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2; Final Rule” or “Stage 2 final rule”) that specified the Stage 2 criteria that EPs, eligible hospitals, and CAHs would have to meet in order to qualify for incentive payments. In addition, the Stage 2 final rule finalized payment adjustments and other program participation requirements under Medicare for covered professional and hospital services provided by EPs, eligible hospitals, and CAHs failing to demonstrate meaningful use of CEHRT, and finalized the revision of certain Stage 1 criteria, and finalized criteria that applied regardless of stage.

In the December 7, 2012 **Federal Register** (77 FR 72985), CMS and ONC jointly published an interim final rule with comment period (IFC) titled “Health Information Technology: Revisions to the 2014 Edition Electronic Health Record Certification Criteria; and Medicare and Medicaid Programs; Revisions to the Electronic Health Record Incentive Program” (December 7, 2012 IFC). The Department of Health and Human Services (HHS) issued the IFC to replace the Data Element Catalog (DEC) standard and the Quality Reporting Document Architecture (QRDA) Category III standard adopted in the final rule published on September 4, 2012 in the **Federal Register** with updated versions of those standards. The December 7, 2012 IFC also revised the Medicare and Medicaid EHR Incentive Programs by—

- Adding an alternative measure for the Stage 2 meaningful use (MU) objective for hospitals to provide structured electronic laboratory results to ambulatory providers;
- Correcting the regulation text for the measures associated with the objective for hospitals to provide patients the ability to view online, download, and transmit information about a hospital admission; and
- Making the case number threshold exemption for CQM reporting applicable for eligible hospitals and CAHs beginning with FY 2013.

The December 7, 2012 IFC also provided notice of our intention to issue technical corrections to the electronic specifications for CQMs released on October 25, 2012.

In the September 4, 2014 **Federal Register** (79 FR 52910 through 52933) CMS and ONC published a final rule titled “Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program for 2014 and Other Changes to the EHR Incentive Program; and Health Information

Technology: Revisions to the Certified EHR Technology Definition and EHR Certification Changes Related to Standards; Final Rule” (“2014 CEHRT Flexibility final rule”). Due to issues related to EHR technology certified to the 2014 Edition availability delays, the 2014 CEHRT Flexibility final rule included policies allowing EPs, eligible hospitals, and CAHs that could not fully implement EHR technology certified to the 2014 Edition for an EHR reporting period in 2014 to continue to use one of the following options for reporting periods in CY 2014 and FY 2014, respectively—

- EHR technology certified to the 2011 Edition; or
- A combination of EHR technology certified to the 2011 Edition and EHR technology certified to the 2014 Edition for the EHR reporting periods.

These CEHRT options applied only to those providers that could not fully implement EHR technology certified to the 2014 Edition to meet meaningful use for an EHR reporting period in 2014 due to delays in 2014 Edition availability. Although the 2014 CEHRT flexibility final rule did not alter the attestation or hardship exception application deadlines for 2014, it did make changes to the attestation process to support these flexible options for CEHRT. This 2014 CEHRT Flexibility final rule also discussed the provisions of the December 7, 2012 IFC and finalized policies relating to the provisions contained in the December 7, 2012 IFC.

In the November 13, 2014, **Federal Register**, we published an interim final rule with comment period, under the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; Final Rule (79 FR 67976 through 67978) (November 13, 2014 IFC). Under this November 13, 2014 IFC, we recognized a hardship exception for EPs and eligible hospitals for 2014 under the established category of extreme and uncontrollable circumstances in accordance with the Secretary’s discretionary authority. To accommodate this hardship exception, we further extended the hardship application deadline for EPs and eligible hospitals to November 30 for 2014 only. We also amended the regulations to allow CMS to specify a later hardship application deadline for certain hardship categories for EPs, eligible hospitals, and CAHs.

For Stages 1 and 2, CMS and ONC worked closely to ensure that the definition of meaningful use of CEHRT

and the standards and certification criteria for CEHRT were coordinated. Current ONC regulations may be found at 45 CFR part 170. For this Stage 3 proposed rule, CMS and ONC will again work together to align our regulations.

We urge those interested in this Stage 3 proposed rule to also review the ONC 2015 Edition proposed rule, which is published elsewhere in this **Federal Register**. Readers may also visit: <http://www.cms.hhs.gov/EHRincentiveprograms> and <http://www.healthit.gov> for more information on the efforts at the Department of Health and Human Services (HHS) to advance HIT initiatives.

II. Provisions of the Proposed Regulations

A. Meaningful Use Requirements, Objectives, and Measures for 2017 and Subsequent Years

1. Definitions Across the Medicare Fee-for-Service, Medicare Advantage, and Medicaid Programs

a. Uniform Definitions

As discussed in both the Stage 1 and 2 final rules, we finalized several uniform definitions applicable for the Medicare FFS, Medicare Advantage, and Medicaid EHR Incentive Programs. We set forth these uniform definitions in part 495 subpart A of the regulations. We propose to maintain these definitions, unless stated otherwise in this proposed rule. (For further discussion of the uniform definitions finalized previously, we refer readers to the Stage 1 and Stage 2 final rules at 75 FR 44317 through 44321 and 77 FR 53972).

As discussed in sections II.A.1.c.(1) and (2) of this proposed rule, we are proposing a single set of criteria for meaningful use (“Stage 3”) in order to eliminate the varying stages of the EHR Incentive Programs. We propose that this Stage 3 definition of meaningful use would be optional for providers in 2017 and mandatory for all providers beginning in 2018. To support Stage 3, we propose revising the uniform definitions under 42 CFR 495.4 for “EHR reporting period” and “EHR reporting period for a payment adjustment year,” as explained later in this section. The proposed revisions to these uniform definitions include eliminating the current 90-day EHR reporting period for EPs, eligible hospitals, and CAHs demonstrating meaningful use for the first time, and instead creating a single EHR reporting period aligned to the calendar year. The proposed removal of the 90-day EHR reporting period would not apply to

Medicaid EPs and eligible hospitals demonstrating meaningful use for the first time. We believe eliminating the 90-day EHR reporting period for most providers would simplify reporting, by aligning providers on the same EHR reporting timeline across all settings. In addition, a single EHR reporting period on the calendar year would align the EHR Incentive Program with other CMS quality reporting programs using certified EHR technology such as the Hospital IQR Program and PQRS. Finally, a single EHR reporting period based on the calendar year allows for a single attestation period, thereby enabling the HHS systems to better capture data, conduct enhanced stress testing and issue resolution, and improve quality assurance of systems before each deployment. We detail the proposed revisions to each of the uniform definitions later in this section.

b. Meaningful EHR User

In the Stage 3 proposed rule, we propose to modify the definition of “Meaningful EHR User” under 42 CFR 495.4 to include the Stage 3 objectives and measures defined at § 495.7.

The definition of a “Meaningful EHR User” under the Act requires the use of certified electronic health record technology (CEHRT) (see, for example, section 1848(o)(2) of the Act). We note that the term CEHRT is a defined term for the purpose of meeting the objectives of the EHR Incentive Programs (defined at § 495.4). The term references ONC’s certification criteria for a “Base EHR,” other ONC certification criteria required in the EHR Incentive Programs and the definition of a “Meaningful EHR User.” References to CEHRT within this proposed rule are to certification criteria that are required for purposes of the EHR Incentive Programs. We recognize that CEHRT is just one form of health IT. For this reason, this proposed rule also includes references to “health IT” where appropriate to capture the

broader category of technologies where applicable.

c. Definition of Meaningful Use

(1) Considerations in Defining Meaningful Use

In sections 1848(o)(2)(A) and 1886(n)(3)(A) of the Act, the Congress identified the broad goal of expanding the use of EHRs through the concept of meaningful use. Section 1903(t)(6)(C) of the Act also requires that Medicaid providers adopt, implement, upgrade or meaningfully use CEHRT if they are to receive incentives under Title XIX. CEHRT used in a meaningful way is one piece of the broader HIT infrastructure needed to reform the health care system and improve health care quality, efficiency, and patient safety. This vision of reforming the health care system and improving health care quality, efficiency, and patient safety should inform the definition of meaningful use.

As we explained in the Stage 1 and Stage 2 rules, we seek to balance the sometimes competing considerations of health system advancement (for example, improving health care quality, encouraging widespread EHR adoption, promoting innovation) and minimizing burdens on health care providers given the short timeframe available under the HITECH Act.

Based on public and stakeholder input received during our Stage 1 rule, we laid out a phased approach to meaningful use. Such a phased approach encompasses reasonable criteria for meaningful use based on currently available technology capabilities and provider practice experience, and builds up to a more robust definition of meaningful use as technology and capabilities evolve. The HITECH Act acknowledges the need for this balance by granting the Secretary the discretion to require more stringent measures of meaningful use over time. Ultimately, consistent with other provisions of law, meaningful use of

CEHRT should result in health care that is patient centered, evidence-based, prevention-oriented, efficient, and equitable.

As stated in the Stage 2 final rule (77 FR 53973), we anticipated the Stage 3 criteria for meaningful use would focus on promoting improvements in quality, efficiency, and safety leading to improved health outcomes. We also anticipated that Stage 3 would focus on clinical decision support for national high priority conditions; improving patient access to self-management tools; improving access to comprehensive patient data through robust, secure, patient-centered health information exchange; and improvements in population health.

For this Stage 3 proposed rule, we seek to streamline the criteria for meaningful use. We intend to do this by—

- Creating a single stage of meaningful use objectives and measures (Stage 3), which would be optional for all providers in 2017 and mandatory for all providers in 2018;
- Allowing providers flexible options for 2017;
- Changing the EHR reporting period to a full calendar year for all providers; and
- Aligning with other CMS quality reporting programs using certified health IT such as PQRS and Hospital IQR for clinical quality measurement.

(a) Meaningful Use Stages

Under the phased approach to meaningful use, we updated the criteria for meaningful use through staggered rulemaking, which covered Stages 1 and 2 of the EHR Incentive Program. For further explanation of the criteria we finalized under Stages 1 and 2, including the recent final rule extending Stage 2, we refer readers to 75 FR 44314 through 44588, 77 FR 53968 through 54162, and 79 FR 52910 through 52933. The current progression of the stages is outlined in Table 2.

TABLE 2—STAGE OF MEANINGFUL USE CRITERIA BY FIRST PAYMENT YEAR

First payment year	Stage of meaningful use										
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
2011	1	1	1	* 1 or 2	2	2	3	3	TBD	TBD	TBD
2012		1	1	* 1 or 2	2	2	3	3	TBD	TBD	TBD
2013			1	* 1	2	2	3	3	TBD	TBD	TBD
2014				* 1	1	2	2	3	3	TBD	TBD
2015					1	1	2	2	3	3	TBD
2016						1	1	2	2	3	3
2017							1	1	2	2	3

* 3-month quarter EHR reporting period for Medicare and continuous 90-day EHR reporting period (or 3 months at Stage option) for Medicaid EPs. All providers in the first year in 2014 use any continuous 90-day EHR reporting period.

In the Stage 2 final rule (77 FR 53974), we also stated that we would indicate in future rulemaking our intent for the potential development of stages or further criteria beyond Stage 3. In this proposed rule, we intend for Stage 3 to be the final stage in meaningful use and that no further stages would be developed. However, we understand that multiple technological and clinical care standard changes associated with EHR technology may result in the need to consider changes to the objectives and measures of meaningful use under the EHR Incentive Programs. Accordingly, we note that, as circumstances warrant, we would consider addressing such changes in future rulemaking.

As shown in Table 2, providers in any given year may be participating in 1 of 3 different stages of the EHR Incentive Programs in addition to other CMS quality reporting programs using certified health IT such as PQRS and Hospital IQR. Through listening sessions, correspondence, and public comment forums, providers expressed frustration regarding the competing reporting requirements of multiple CMS programs, and the overall challenge of planning and reporting on the complex and numerous meaningful use requirements, including the need to manage changing processes, workflows, and reporting systems. In addition, group practices with EPs in different stages of meaningful use have to simultaneously support multiple stages of the program in order to demonstrate meaningful use for each EP. Meanwhile, if the current 3-stage framework continues, HHS and state systems would be required to support all 3 stages of the EHR Incentive Programs in perpetuity with extensive implementation of complex processes to accept submissions, analyze data, and coordinate systems.

Providers have expressed ongoing concern that the EHR Incentive Programs are complicated, not focused on clinical reality and workflow, and stifling to innovation in health IT development. Specifically, providers have expressed concerns about the number of Stage 1 and 2 objectives and measures becoming obsolete or lacking any link to improving outcomes. In addition, providers have expressed concern that continued focus on Stage 1 measures impedes current and potential future innovation in advanced utilization of health information technology. Providers worry that Stage 3 of meaningful use would exacerbate these existing concerns.

The certified EHR technology requirements within the EHR Incentive Programs and included in ONC's Health IT Certification Program have resulted in considerable increases in certified EHR technology adoption among providers and are paving the way for more comprehensive, patient-centered care across the care continuum. We recognize that while these advancements have been beneficial there are concerns, as stated previously, that require careful examination to ensure the sustainability and efficacy of the program going forward—as HHS moves to further encourage new uses of health IT and support the developing health IT infrastructure beyond the strides already made. Therefore, we seek to set a new foundation for this evolving program by proposing a number of changes to meaningful use. First, we propose a definition of meaningful use that would apply beginning in 2017. This definition of meaningful use, although referred to as “Stage 3”, would be the only definition for the Medicare and Medicaid EHR Incentive Programs, and would incorporate certain requirements and aspects of Stages 1 and 2. Beginning with 2018, we propose

to require all EPs, eligible hospitals, and CAHs, regardless of their prior participation in the EHR Incentive Program, to satisfy the requirements, objectives, and measures of Stage 3. However, for 2017, we propose that Stage 3 would be optional for providers. This option would allow for a provider to move on to Stage 3 in 2017 or remain at Stage 2, or for some providers to remain at Stage 1, depending on their participation timeline. For example, under this proposal, a provider in Stage 2 in 2016 could choose to remain in Stage 2 in 2017 or progress to Stage 3. In contrast to our rulemaking in 2014 to accommodate the use of multiple Editions to meet the definitions of CEHRT during the EHR reporting periods in that year, this policy is based on the provider selection of the objectives and measures for their demonstration of meaningful use in 2017. Both the EHR technology certified to the 2014 Edition and the EHR technology certified to the 2015 Edition will support attestations for Stage 1 or Stage 2 in 2017. In addition, the development and certification process for EHR technology products is not dependent on this selection by individual providers. Therefore, we do not expect that this policy would affect the availability of EHR technology certified to the 2015 Edition in 2017 or the ability of an individual provider to implement EHR technology certified to the 2015 Edition during the year regardless of which stage they choose for their EHR reporting period in 2017. Therefore, we are proposing in section II.A.2.b. that all providers would be required to use EHR technology certified to the 2015 Edition for a full calendar year for the EHR reporting period in 2018. The revised timeline based on these proposals is outlined in Table 3.

TABLE 3—STAGE OF MEANINGFUL USE CRITERIA BY FIRST YEAR

First year as a meaningful EHR user	Stage of meaningful use										
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021 and future years
2011	1	1	1	*2	2	2	2 or 3	3	3	3	3
2012		1	1	*2	2	2	2 or 3	3	3	3	3
2013			1	1	2	2	2 or 3	3	3	3	3
2014				1	1	2	2 or 3	3	3	3	3
2015					1	1	1, 2 or 3	3	3	3	3
2016						1	1, 2 or 3	3	3	3	3
2017							1, 2 or 3	3	3	3	3
2018 and future years								3	3	3	3

* Please note, a provider scheduled to participate in Stage 2 in 2014, who instead elected to demonstrate stage 1 because of delays in availability of EHR technology certified to the 2014 Edition, is still considered a stage 2 provider in 2014 despite the alternate demonstration of meaningful use. In 2015, all such providers are considered to be participating in their second year of Stage 2 of meaningful use.

Please note that the Medicare EHR Incentive Program and the Medicaid EHR Incentive Program have different rules regarding the number of payment years available, the last year for which incentive payments may be received, and the last year to initiate the program and receive an incentive payment. Medicaid EPs and eligible hospitals can receive a Medicaid EHR incentive payment for “adopting, implementing, and upgrading” (AIU) to Certified EHR Technology for their first payment year, which is not reflected in Table 3. The applicable payment years and the incentive payments available for each program are discussed in the Stage 1 final rule (75 FR 44318 through 44320). Although Table 3 outlines a provider’s progression through the stages of meaningful use, it does not necessarily reflect the relation to incentive payments in the Medicare or Medicaid EHR Incentive Programs. We note that some providers may not ever qualify to receive an incentive payment depending on, among other factors, when and whether they successfully demonstrate meaningful use in the EHR Incentive Programs. We intend for the timeline in Table 3 to also apply to those EPs, eligible hospitals, and CAHs that never receive an incentive payment under the EHR Incentive Programs.

We are further proposing that Stage 3 would adopt a simplified reporting structure on a focused set of objectives and associated measures to replace all criteria under Stages 1 and 2. Specifically, we are proposing criteria for meaningful use for EPs, eligible hospitals, and CAHs (optional in 2017 and mandatory beginning in 2018), regardless of a provider’s prior participation in the Medicare and Medicaid EHR Incentive Programs, as described in detail in section II.A.1.c. of this proposed rule. We believe that a single set of objectives would reduce provider burden and allow for greater focus on improving outcomes, enhancing interoperability, and increasing patient engagement. In addition, with all providers participating at the same level, the impact of the scale of participation helps to support growth in health information exchange and patient engagement infrastructure, as more providers participate the ease of participation increases. Finally, the associated measures proposed for Stage 3 in this proposed rule would use advanced EHR functionality and IT-based processes. The requirements, objectives, and measures are outlined further in sections II.A.1.c.(2). of this proposed rule. In order to maintain

clarity in relation to the various rules and stages, provisions outlined in the Stage 1 or Stage 2 final rules, and proposals under this Stage 3 proposed rule, we will maintain the “Stage” designation in order to indicate the rule that contains the provision. The requirements, objectives, and measures proposed as part of this proposed definition of meaningful use would be referred to as “Stage 3”.

We welcome public comment on these proposals.

(b) EHR Reporting Period

In the Stage 1 and Stage 2 final rules, we established that the EHR reporting period for eligible hospitals and CAHs is based on the federal fiscal year (October 1 through September 30). This fiscal year EHR reporting period originally was designed to support coordination between program implementation and CMS payment systems following the development of the EHR Incentive Programs in 2010 to allow for efficient payment of incentives for eligible hospitals and CAHs. However, as the EHR Incentive Program evolved, we found the fiscal year EHR reporting period resulted in varying reporting timelines between provider types (for example, the EHR reporting period for EPs is based on the calendar year) and a shortened timeline for system developers to meet hospital and CAH technology requirements. Enhanced coordination between CMS programs and other system implementation changes have subsequently made it unnecessary to maintain a reporting timeframe for eligible hospitals and CAHs based on the federal fiscal year. Therefore, we are proposing changes to the EHR reporting period beginning with the EHR reporting period in 2017 in order to do all of the following:

- Simplify reporting for providers, especially groups and diverse systems.
- Support further alignment of CMS quality reporting programs using certified health IT such as Hospital IQR and PQRS.
- Simplify HHS system requirements for data capture.
- Provide for greater flexibility, stress testing, and Quality Assurance (QA) of systems before deployment.

In the FY 2015 IPPS final rule (79 FR 49853 through 50449), we aligned the reporting and submission timelines for CQMs for the Medicare EHR Incentive Programs for eligible hospitals and CAHs with the reporting and submission timelines for the Hospital IQR Program on a calendar year basis. This was designed to allow for better alignment between these programs in

light of the directive in section 1886(n)(3)(B)(iii) of the Act to avoid redundant or duplicative reporting. Calendar year reporting on quality data for hospitals allows for greater efficiency in measure development, the electronic specification of measures, and the update and deployment of measure logic and value sets for electronic clinical quality measures. The FY 2014 IPPS final rule (78 FR 50904) clarified that eligible hospitals and CAHs demonstrating meaningful use for the first time in FY 2014 and reporting on CQMs electronically must report on a 3-month quarter in FY 2014, rather than on a continuous 90-day period. Such changes not only better align program reporting but also allow for better data integrity as previously discussed in the Stage 2 final rule (77 FR 53974 through 53975) and further discussed in section II.B.1.b. of this proposed rule.

(i) Calendar Year Reporting

We are proposing to change the definitions of “EHR reporting period” and “EHR reporting period for a payment adjustment year” under § 495.4 for EPs, eligible hospitals, and CAHs such that the EHR reporting period would be one full calendar year, with a limited exception under the Medicaid EHR Incentive Program for providers demonstrating meaningful use for the first time as discussed later in this section and in section II.A.2.b. of this proposed rule. This would allow for the full alignment of the EHR reporting timeline for the meaningful use objectives and associated measures and the CQMs, and align the timing of reporting by EPs, eligible hospitals, and CAHs. We propose this change would apply beginning in CY 2017. For example, for the incentive payments for the 2017 payment year, the EHR reporting period for EPs, eligible hospitals, and CAHs would be the full 2017 calendar year. We note that the incentive payments under Medicare FFS and Medicare Advantage (MA) (sections 1848(o), 1886(n), 1814(l)(3), 1853(l) and (m) of the Act) will end before 2017. However, under this proposed change, EPs and eligible hospitals that seek to qualify for an incentive payment under Medicaid would have a full calendar year EHR reporting period if they are not demonstrating meaningful use for the first time. For the payment adjustments under Medicare, we discuss the timing of the EHR reporting period in relation to the payment adjustment year in section II.D.2. of this proposed rule.

This proposal would mean that eligible hospitals and CAHs would have

a reporting gap for the objectives and measures of meaningful use consisting of the 3-month quarter from October 1, 2016 through December 31, 2016. Depending on future rulemaking, eligible hospitals and CAHs may still be required to report on CQMs over this time. The next EHR reporting period for eligible hospitals and CAHs to collect data on the objectives and measures of meaningful use would then begin on January 1, 2017 and end on December 31, 2017. Eligible hospitals and CAHs would then report on a full calendar year basis from that point forward.

(ii) Eliminate 90-Day EHR Reporting Period

We are further proposing to eliminate the 90-day EHR reporting period for new meaningful EHR users beginning in 2017, with a limited exception for Medicaid EPs and eligible hospitals demonstrating meaningful use for the first time. This would allow for a single EHR reporting period of a full calendar year for all providers across all settings. Specifically, we propose to eliminate the EHR reporting period of any continuous 90 days for EPs, eligible hospitals, and CAHs that are demonstrating meaningful use for the first time. Those providers instead would have an EHR reporting period of a full calendar year, as described previously. However, as discussed in section II.A.2.b. of this proposed rule, we propose to maintain the 90-day EHR reporting period for a provider's first payment year based on meaningful use for EPs and eligible hospitals participating in the Medicaid EHR Incentive Program. We propose corresponding revisions to the definitions of "EHR reporting period" and "EHR reporting period for a payment adjustment year" under § 495.4. We propose these changes would apply beginning in CY 2017.

As stated previously, all providers would attest based on a single EHR reporting period consisting of one full calendar year for the applicable objectives and measures of meaningful use in 2017 and subsequent years. These providers would submit their data in the 2 months following the close of the EHR reporting period. For further information on the submission methods, see section II.D.9.b. of this proposed rule.

We welcome public comment on these proposals.

(iii) State Flexibility for Stage 3 of Meaningful Use

Consistent with our approach under both Stage 1 and 2, we propose to continue to offer states flexibility under

the Medicaid EHR Incentive Program in Stage 3 by adding a new provision at § 495.316(d)(2)(iii) subject to the same conditions and standards as the Stage 2 flexibility policy. Under Stage 3, state flexibility would apply only with respect to the public health and clinical data registry reporting objective outlined under section II.A.1.c.(1)(b)(i) of this proposed rule.

For Stage 3 of meaningful use, we would continue to allow states to specify the means of transmission of the data and otherwise change the public health agency reporting objective as long as it does not require functionality greater than what is required for Stage 3 and included in the 2015 Edition proposed rule elsewhere in this issue of the **Federal Register**.

We welcome comment on this proposal.

(2) Criteria for Meaningful Use Stage 3

In the Stage 1 and Stage 2 final rules, meaningful use included the concept of a core and a menu set of objectives. Each objective had associated measures that a provider needed to meet as part of demonstrating meaningful use of CEHRT. In Stage 2 of meaningful use, we also combined some of the objectives of Stage 1 and incorporated them into objectives for Stage 2. For example, we combined the objectives of maintaining an up-to-date problem list, active medication list, and active medication allergy list with the objective of providing a summary of care record for each transition of care or referral through required fields in the summary of care document (77 FR 53990 through 53991 and 77 FR 54013 through 54016). We did this to allow for the more advanced use of EHR technology functions to support clinical processes, and to eliminate the need for providers to individually report on measures that were often already incorporated in workflows and for which many providers were already meeting the threshold (known as "topping out"). In the Stage 2 final rule (77 FR 53973), we signaled that the Stage 2 core and menu objectives would all be included in the Stage 3 proposal for meaningful use.

Since the publication of the Stage 2 final rule, we have reviewed meaningful use performance from both a qualitative and quantitative perspective including analyzing performance rates, reviewing CEHRT functionalities and standards, and considering information gained by engaging with providers through listening sessions, correspondence, and open forums like the HIT Policy Committee. The data support a number of key points for consideration:

- Providers are performing higher than the thresholds for some of the meaningful use measures using some EHR functionalities that—prior to the Stage 1 and Stage 2 final rules—were not common place (such as the maintenance of problem lists).
 - Providers in different specialties and settings implemented CEHRT and met objectives in different ways.
 - Providers express support for reducing the reporting burden on measures that have "topped out."
 - Providers expressed support for advanced functionality that would offer value to providers and patients.
 - Providers expressed support for flexibility regarding how objectives are implemented in their practice settings.
 - Providers in health systems and large group practices expressed frustration about the reporting burden of having to compile multiple reports spanning multiple stages and objectives.
- Since the EHR Incentive Programs began in 2011, stakeholder associations and providers have requested that we consider changes to the number of objectives and measures that providers must meet to demonstrate meaningful use of certified EHR technology under the EHR Incentive Programs. These recommendations also extended to considerations for the structure of Stage 3 of meaningful use. Many of these recommendations include allowing a provider to fail any two objectives (in effect making all objectives "menu" objectives) and still meet meaningful use, or to allow providers to receive an incentive payment or avoid a downward payment adjustment based on varied percentages of performance, and removing all measure thresholds. We have reviewed these recommendations and have declined to follow this course for a number of reasons.
- First, the statute specifically requires the Secretary to seek to improve the use of EHR and health care quality over time by requiring more stringent measures of meaningful use (see, for example, section 1848(o)(2)(A)(iii) of the Act). This is one reason why we established stages of meaningful use to move providers along a progression from adoption to advanced use of certified EHR technology. Therefore, we intend to continue to use measure thresholds that may increase over time, and to incorporate advanced use functions of certified EHR technology into meaningful use objectives and measures.

Second, there are certain objectives and measures which capture policies specifically required by the statute as core goals of meaningful use of certified EHR technology, such as electronic

prescribing for EPs, health information exchange, and clinical quality measurement (see sections 1848(o)(2)(A) and 1886(n)(3)(A) of the Act). Specific to the health information exchange, the statute requires certified EHR technology connected in a manner that provides for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination.

Further, the statute requires that the certified EHR technology which providers must use shall be a “qualified EHR” as defined in section 3000(13) of the Public Health Service Act as an electronic record of health-related information on an individual that includes patient demographic and clinical health information, such as medical history and problem lists; and has the capacity to—

- Provide clinical decision support;
- Support physician order entry;
- Capture and query information relevant to health care quality; and
- Exchange electronic health information with, and integrate such information from, other sources (see section 1848(o)(4) of the Act).

The objectives that address these requirements are integral to the foundational goals of the program, which would be undermined if providers were allowed to fail to meet these objectives and still be considered meaningful EHR users. For these reasons, we intend to continue to require providers to meet the objectives and measures of meaningful use as required for the program, rather than allowing providers to fail any two objectives of their choice or making all objectives menu objectives.

Finally, while we understand providers are seeking to reduce the overall burden of reporting, we do not believe these recommendations accomplish that goal. Adding all objectives and measures to the menu set and allowing for varying degrees of participation may add complexity for the individual provider seeking to determine how they can meet the requirements and demonstrate meaningful use of certified EHR technology. We instead are proposing (as discussed in sections II.A.1. and II.B. of this proposed rule) to reduce provider burden and simplify the program by aligning reporting periods and CQM reporting. In addition, the statute provides that in selecting measures for the EHR Incentive Program, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required, including reporting under the PQRS and Hospital IQR Program (see sections 1848(o)(2)(B)(iii) and

1886(n)(3)(B)(iii) of the Act). Although the statute refers to redundant or duplicative reporting in the context of other CMS quality reporting programs, we believe it is also useful and appropriate to consider whether there are redundant or duplicative aspects of the objectives and measures of Stages 1 and 2 of meaningful use as we develop policies for Stage 3.

To that end, we have analyzed the objectives and measures of meaningful use in Stage 1 and Stage 2 of the program to determine where measures are redundant, duplicative, or have “topped out.” “Topped out” is the term used to describe measures that have achieved widespread adoption at a high rate of performance and no longer represent a basis upon which provider performance may be differentiated. We considered redundant objectives and measures to include those where a viable health IT-based solution may replace paper-based actions, such as the Stage 2 Clinical Summary objective (77 FR 54001 and 54002). We considered duplicative objectives and measures to include those where some aspect is also captured in the course of meeting another objective or measure, such as recording vital signs which is also required as part of the summary of care document under the Stage 2 Summary of Care objective (77 FR 54013 through 54021). Finally, measures which have “topped out” do not provide a meaningful gain in the effort to improve the use of EHR and health care quality over time by requiring more stringent measures of meaningful use as directed in the statute (see section 1848(o)(2)(A)(iii) of the Act). For further discussion of “topped out” measures, we direct readers to section II.A.2.a. of this proposed rule.

Therefore, our proposals for Stage 3 would continue the precedent of focusing on the advanced use of certified EHR technology. They would reduce the reporting burden; eliminate measures that are now redundant, duplicative, and “topped out”; create a single set of objectives for all providers with limited variation between EPs, eligible hospitals, and CAHs as necessary; and provide flexibility within the objectives to allow providers to focus on implementations that support their practice.

(a) Topped Out Objectives and Measures

In other contexts and CMS programs, CQMs are regularly evaluated to determine whether they have “topped out,” which means generally that measure performance among providers is so high and unvarying that meaningful distinctions and

improvements in performance can no longer be made. Examples of this type of evaluation are found in the Hospital Inpatient Quality Reporting (IQR) program, the Hospital-Value Based Purchasing (HVBP) program, the End-Stage Renal Disease (ESRD) Quality Initiative, and within the National Quality Forum (NQF) endorsement and maintenance process for CQMs. We believe that quality measures, once “topped-out,” represent care standards that have been widely adopted. We believe such measures should be considered for removal from program reporting because their associated reporting burden may outweigh the value of the quality information they provide and because, in some cases, the inclusion of these measures may impact the ability to differentiate among provider performance as a whole for programs which use baseline and benchmarking based on measure performance scores. Therefore, measures are regularly subject to an evaluation process to identify their continued efficacy. This evaluation process is used to determine whether a measure is “topped out” and, if so, whether that measure should be removed from program reporting requirements. We note that both the identification and the determination of a measure are part of the process as a measure may be identified as topped out, but still be determined useful as a measure for a specific program because of other factors that merit continued use of the measure.

While the EHR Incentive Program does not use a benchmarking system to rate the overall and relative performance of providers as part of the definitions of meaningful use; we are proposing to adopt an approach to evaluate whether objectives and measures have become “topped out” and, if so, whether a particular objective or measure should be considered for removal from reporting requirements. We propose to apply the following two criteria, which are similar to the criteria used in the Hospital IQR and HVBP Programs (79 FR 50203): 1—Statistically indistinguishable performance at the 75th and 99th percentile, and 2—performance distribution curves at the 25th, 50th, and 75th percentiles as compared to the required measure threshold.

An example of a current Stage 1 objective which would be considered “topped out” under this approach is the objective to record demographics (75 FR 44340 through 44343). For the record demographics objective, we reviewed performance data submitted by providers through attestation and

determined that across all years of participation, the 75th percentile is performing at 99.8 percent with the 99th percentile performing at 100 percent. In addition, the 25th, 50th, and 75th percentiles are all performing with minimal variance and significantly higher than the measure threshold of 50 percent, with performance rates at 97 percent, 99 percent, and 100 percent respectively for eligible hospitals and 92 percent, 98 percent and 100 percent respectively for EPs in Stage 1.¹ For more information on the performance data, please see the EHR Incentive Programs Objective and Measure Performance Report by Percentile available at <http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>. We further note that this particular objective may also be considered duplicative as further discussed in section II.A.2.c. of this proposed rule, as the functionality which supports the objective within the EHR is also used in other objectives such as the objective to provide patient-specific education resources (77 FR 54011 through 54012) and the Stage 2 summary of care objective (77 FR 54013 through 54021). Therefore, this is an example of an objective that we determined is topped out and may no longer provide value as an independent objective in the program.

We welcome public comments on our proposed approach for topped out objectives and measures.

(b) Electronic Versus Paper-Based Objectives and Measures

In Stages 1 and 2, we require or allow providers the option to include paper-based formats for certain objectives and measures. For these objectives and measures, providers would print, fax, mail, or otherwise produce a paper document and manually count these actions to include in the measure calculation. Examples of these include: The provision of a non-electronic summary of care document for a transition or referral to meet the measure at § 495.6(j)(14)(i) for EPs and for eligible hospitals and CAHs at § 495.6(l)(11)(i): “The [provider] who transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals;” and the provision of paper-based patient education materials measure for at § 495.6(j)(12)(i)

for EPs and § 495.6(l)(9)(i) requiring: “Patient-specific education resources identified by Certified EHR Technology are provided to patients for more than 10 percent of all unique patients with office visits seen by the EP [or discharged from the eligible hospital or CAH] during the EHR reporting period.” Each of these measures may be met using a non-electronic format or action, and we propose to discontinue this policy for Stage 3. We recognize the strides that providers have made in the use of CEHRT and as we move forward in MU, it is appropriate to remove the earlier iterations of objectives and measures that were designed to support beginning EHR use and instead focus on objectives that are based solely on electronic use of data. This does not imply that we do not support the continued use of paper-based materials in a practice setting. Some patients may prefer to receive a paper version of their clinical summary or may want to receive education items or reminders on paper or some other method that is not electronic. We strongly recommend that providers continue to provide patients with visit summaries, patient health information, and preventative care recommendations in the format that is most relevant for each individual patient and easiest for that patient to access. In some cases, this may include the continued use of non-IT-based resources. We are simply proposing that paper-based formats would not be required or allowed for the purposes of the objectives and measures for Stage 3 of meaningful use. We welcome public comments on this proposal.

(c) Advanced EHR Functions

As discussed in section II.A.1.c.(2).(a). of this proposed rule, we are proposing to simplify requirements for meaningful use through an analysis of existing objectives and measures for Stages 1 and 2 to determine if they are redundant, duplicative, or “topped out”. We note that some of the objectives and measures which meet these criteria involve EHR functions that are required by the statutory definition of “certified EHR technology” (see section 1848(o)(4) of the Act, which references the definition of “qualified EHR” in section 3000(13) of the Public Health Service Act) which a provider must use to demonstrate meaningful use. The objectives and measures proposed for Stage 3 would include uses of these functions in a more advanced form. For example, patient demographic information is included in an electronic summary of care document called a consolidated clinical document architecture (CCDA) provided during a

transition of care in the Stage 2 Summary of Care objective and measures (77 FR 54013 through 54021), which represents a more advanced use of the EHR function than in the Stage 1 and 2 objective to record patient demographic information (77 FR 53991 through 53993).

We adopted a multi-part approach to identify the objectives and measures which would be proposed for providers to demonstrate meaningful use for Stage 3. This methodology included the analysis mentioned previously of existing Stage 1 and 2 objectives and measures, and provider performance; a review and consideration of the HIT Policy Committee recommendations (which are publicly available for review at: <http://www.healthit.gov/facas/health-it-policy-committee/health-it-policy-committee-recommendations-national-coordinator-health-it>); and an evaluation of how the potential objectives and measures align with the foundational goals of the program defined in the HITECH Act.

In the Stage 2 proposed and final rules, we often identified the HIT Policy Committee recommendations as part of our discussion of the specific objectives and measures, for example in the Stage 2 CPOE objective at 77 FR 43985. In this proposed rule for Stage 3 of meaningful use, although we have considered the HIT Policy Committee’s recommendations in developing our proposed policies, we are not referencing the recommendations in each individual proposed objective and measure as there are multiple factors that contribute to the selection of each proposed objective and measure. In addition, many of the HIT Policy Committee recommendations address functions and standards that are part of the advanced use of certified EHR technology captured by one or more objectives proposed for Stage 3 of meaningful use. For example, the HIT Policy Committee has recommended an expansion of demographic data captured as structured data as well as a change to the related standards for use. However, this function and standard is required for certification of EHR technology for meaningful use and it is a required field for an electronic summary of care document for health information exchange. It is also to be included in the information accessible to a patient within their electronic patient record. Therefore, to provide clarity for readers, we provide a notation within Table 4 to identify alignment between the proposed Stage 3 objectives and measures and the recommendations of the HIT Policy Committee for Stage 3 of meaningful

¹ Data may be found on the CMS Web site data and program reports page: <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>.

use. We direct readers to the HIT Policy Committee recommendations available on HealthIT.gov for further information (<http://www.healthit.gov/facas/health-it-policy-committee/health-it-policy-committee-recommendations-national-coordinator-health-it>).

As mentioned previously, the statute includes certain foundational goals and requirements for meaningful use of

certified EHR technology and the functions of that technology. Therefore, after review of the existing Stage 1 and Stage 2 objectives and measures of meaningful use, the recommendations of the HIT Policy Committee, and the foundational goals and requirements under the HITECH Act; we have identified eight key policy areas which represent the advanced use of EHR

technology and align with the program’s foundational goals and overall national health care improvement goals, such as those found in the CMS National Quality Strategy.² These eight policy areas provide the basis for the proposed objectives and measures for Stage 3 of meaningful use. They are included in Table 4 as follows:

TABLE 4—OBJECTIVES AND MEASURES FOR MEANINGFUL USE IN 2017 AND SUBSEQUENT YEARS

Program goal/objective	Delivery system reform goal alignment
Protect Patient Health Information	Foundational to Meaningful Use and Certified EHR Technology *.
Electronic Prescribing (eRx)	Recommended by HIT Policy Committee.
Clinical Decision Support (CDS)	Foundational to Meaningful Use.
Computerized Provider Order Entry (CPOE)	National Quality Strategy Alignment.
Patient Electronic Access to Health Information	Foundational to Certified EHR Technology.
Coordination of Care through Patient Engagement	Recommended by HIT Policy Committee.
Health Information Exchange (HIE)	National Quality Strategy Alignment.
Public Health and Clinical Data Registry Reporting	Recommended by HIT Policy Committee.
	National Quality Strategy Alignment.
	Recommended by HIT Policy Committee.
	National Quality Strategy Alignment.

* See, for example, sections 1848(o)(2) and (4) of the Act.

These objectives build on the measures and EHR functionalities from the Stage 1 final rule and the Stage 2 final rule to advance the core functions of EHRs in a clinically relevant way that benefits providers and patients.

Under this proposal, which would apply to Stage 3 of meaningful use in 2017 and subsequent years, providers must successfully attest to these eight objectives and the associated measures (or meet the exclusion criteria for the applicable measure). As mentioned previously, the statute requires the Secretary to seek to improve the use of EHR and health care quality over time by requiring more stringent measures of meaningful use (see section 1848(o)(2)(A)(iii) of the Act). While we are proposing to simplify the program by removing topped-out, redundant, and duplicative measures and aligning reporting periods for providers; we are maintaining the push to improve the use of EHRs over time through these eight objectives and the associated measures proposed for Stage 3 of meaningful use. These proposed objectives and measures include advanced EHR functions, use a wide range of structured standards in CEHRT, employ increased thresholds

over similar Stage 1 and 2 measures, support more complex clinical and care coordination processes, and require enhanced care coordination through patient engagement through a flexibility structure of active engagement measures.

These proposed objectives and their associated measures are further discussed in section II.A.1.(c).(2). of this proposed rule. CMS and ONC will continue to monitor and review performance on the objectives and measures finalized for Stage 3 to continue to evaluate them for rigor and efficacy and, if necessary, propose changes in future rulemaking.

(d) Flexibility Within Meaningful Use Objectives and Measures

We are proposing to incorporate flexibility within certain objectives proposed for Stage 3 for providers to choose the measures most relevant to their unique practice setting. This means that as part of successfully demonstrating meaningful use, providers would be required to attest to the results for the numerators and denominators of all measures associated with an objective; however, a provider

would only need to meet the thresholds for two of the three associated measures. The proposed Stage 3 objectives including flexible measure options are as follows:

- Coordination of Care through Patient Engagement—Providers must meet the thresholds of two of three measures and must attest to the numerators and denominators of all three measures.
- Health Information Exchange—Providers must meet the thresholds of two of three measures and must attest to the numerators and denominators of all three measures.
- Public Health Reporting—EPs must report on three measures and eligible hospitals and CAHs must report on four measures.

We propose that if a provider meets the exclusion criteria for a particular measure within an objective which allows providers to meet the thresholds for two of three measures (namely, the Coordination of Care through Patient Engagement objective and the Health Information Exchange objective), the provider may exclude the measure and must meet the thresholds of the remaining two measures to meet the

²The National Quality Strategy: “HHS National Strategy for Quality Improvement in Health Care” <http://www.ahrq.gov/workingforquality/about.htm>.

objective. If a provider meets the exclusion criteria for two measures for such an objective, the provider may exclude those measures and must meet the threshold of the remaining measure to meet the objective. If a provider meets the exclusion criteria for all three measures for such an objective, the provider may exclude those measures and would be considered to have met the objective.

We discuss the proposed policy for exclusions for the public health reporting objective as well as the exclusion criteria in further detail within the individual objectives and measures in section II.A.1.(c).(2). of this proposed rule.

(e) EPs Practicing in Multiple Practices/ Locations

For Stage 3, we propose to maintain the policy from the Stage 2 final rule (77 FR 53981) which states that to be a meaningful user, an EP must have 50 percent or more of his or her outpatient encounters during the EHR reporting period at a practice/location or practices/locations equipped with CEHRT. An EP who does not conduct at least 50 percent of their patient encounters in any one practice/location would have to meet the 50 percent threshold through a combination of practices/locations equipped with CEHRT. For example, if the EP practices at a federally qualified health center (FQHC) and within his or her individual practice at two different locations, we would include in our review all three of these locations, and CEHRT would have to be available at one location or a combination of locations where the EP has 50 percent or more of his or her patient encounters. If CEHRT is only available at one location, then only encounters at this location would be included in meaningful use assuming this one location represents 50 percent or more of the EP's patient encounters. If CEHRT is available at multiple locations that collectively represent 50 percent or more of the EP's patient encounters, then all encounters from those locations would be included in meaningful use. In the Stage 2 final rule at (77 FR 53981), we defined patient encounter as any encounter where a medical treatment is provided or evaluation and management services are provided. This includes both individually billed events and events that are globally billed, but are separate encounters under our definition.

In addition, in the Stage 2 final rule at (77 FR 53981) we defined a practice/location as equipped with CEHRT if the record of the patient encounter that occurs at that practice/location is

created and maintained in CEHRT. This can be accomplished in the following three ways: CEHRT could be permanently installed at the practice/location, the EP could bring CEHRT to the practice/location on a portable computing device, or the EP could access CEHRT remotely using computing devices at the practice/location. We propose to maintain these definitions for Stage 3.

(f) Denominators

The objectives for Stage 3 of meaningful use include percentage-based measures wherever possible. In the Stage 2 final rule, we included a discussion of the denominators used for the program that included the use of one of four denominators for each of the measures associated with the meaningful use objectives outlined in the Stage 2 final rule at 77 FR 53982 for EPs and 77 FR 53983 for eligible hospitals and CAHs. We focused on denominators because the action that moves something from the denominator to the numerator requires the use of CEHRT by the provider. For Stage 3 we refer readers to each of the proposed objectives and measures for Stage 3 for the specific calculation of each denominator for each measure. Here, we simply outline the general proposals for determining the scope of the measure denominators.

For EPs, the references used to define the scope of the potential denominators for measures include the following:

- Unique patients seen by the EP during the EHR reporting period. The scope for this calculation may be limited to only those patients whose records are maintained in the EHR for the denominator of the measures for objectives other than those referencing "unique patients" as previously established in the Stage 2 final rule at (77 FR 53981). We propose to maintain the policy that EPs who practice at multiple locations or switch CEHRT during the EHR reporting period may determine for themselves the method for counting unique patients in the denominators to count unique patient across all locations equipped with different CEHRT, or to count at each location equipped with CEHRT. In cases where a provider switches CEHRT products at a single location during the EHR reporting period, they also have the flexibility to count a patient as unique on each side of the switch and not across it. EPs in these scenarios must choose one of these methods for counting unique patients and apply it consistently throughout the entire EHR reporting period.

A patient is seen by the EP when the EP has a real time physical encounter with the patient in which they render any service to the patient. We also consider a patient seen through telehealth as a patient "seen by the EP" (telehealth may include the commonly known telemedicine as well as telepsychiatry, telenursing, and other diverse forms of technology-assisted health care). However, in cases where the EP and the patient do not have a real time physical or telehealth encounter, but the EP renders a consultative service for the patient, such as reading an EKG, virtual visits, or asynchronous telehealth, the EP may choose whether to include the patient in the denominator as "seen by the EP." This is necessary so that these providers can avoid reporting a zero in the denominator and be able to satisfy meaningful use. However, we stress that once providers choose, they must maintain that denominator choice for the entire EHR reporting period and for all relevant meaningful use measures.

- Office visits. The denominators of the measures that reference "office visits" may be limited to only those patients whose records are maintained using CEHRT. An office visit is defined as any billable visit that includes the following:

- ++ Concurrent care or transfer of care visits,

- ++ Consultant visits, or
- ++ Prolonged physician service without direct, face-to-face patient contact (for example, telehealth).

- All medication, laboratory, and diagnostic imaging orders created during the reporting period

- Transitions of care and referrals including at least—

- ++ When the EP is the recipient of the transition or referral, the first encounter with a new patient and encounters with existing patients where a summary of care record (of any type) is provided to the receiving EP; and

- ++ When the EP is the initiator of the transition or referral, transitions and referrals ordered by the EP.

Transitions of care are the movement of a patient from one setting of care to another. Referrals are cases where one provider refers a patient to another, but the referring provider maintains their care of the patient as well. For the purposes of distinguishing settings of care in determining the movement of a patient, we propose that a transition or referral may take place when a patient is transitioned or referred between providers with different billing identities, such as a different National Provider Identifier (NPI) or hospital CMS Certification Number (CCN). We

also propose that in the cases where a provider has a patient who seeks out and receives care from another provider without a prior referral, the first provider may include that transition as a referral if the patient subsequently identifies the other provider of care.

For further explanation of the terms “unique patient,” “seen by the EP,” “office visit,” “transitions of care,” and “referrals,” we refer readers to the discussion at 77 FR 53982 through 53983. For eligible hospitals and CAHs, the references used to define the scope of the potential denominators for measures include the following:

- Unique patients admitted to the eligible hospital’s or CAH’s inpatient or emergency department during the EHR reporting period.

- All medication, laboratory, and diagnostic imaging orders created during the reporting period.

- Transitions of care and referrals including at least—

- ++ When the hospital is the recipient of the transition or referral: all admissions to the inpatient and emergency departments; and

- ++ When the hospital is the initiator of the transition or referral: all discharges from the inpatient department; and after admissions to the emergency department when follow-up care is ordered by an authorized provider.

We propose that the explanation of the terms “unique patients,” “transitions of care,” and “referrals” stated previously for EPs would also apply for eligible hospitals and CAHs, and we refer readers to the discussion of those terms in the hospital context in the Stage 2 final rule (77 FR 53983 and 53984). We propose for Stage 3 to maintain the policy that admissions may be calculated using one of two methods (the observation services method and the all emergency department method), as described for Stage 2 at 77 FR 53984. The method an eligible hospital or CAH chooses must be used uniformly across all measures for all objectives.

We reiterate that all discharges from an inpatient setting are considered a transition of care. We further propose for transitions from an emergency department, that eligible hospitals and CAHs must count any discharge where follow up care is ordered by an authorized provider regardless of the completeness of information available on the receiving provider. The eligible hospital or CAH should determine an internal policy applicable for the identification and capture of a patient’s primary care provider or other relevant care team members for the purposes of

ordering potential follow-up care. This will allow eligible hospitals and CAHs to better differentiate between discharges where care is ordered and discharges to home where no follow up care is ordered.

(g) Patient-Authorized Representatives

In the Stage 3 Coordination of Care through Patient Engagement objective and the Patient Electronic Access objective outlined in section II.A.1.c.(2).(i) of this proposed rule, we propose the inclusion of patient-authorized representatives in the numerators as equivalent to the inclusion of the patient. We recognize that patients often consult with and rely on trusted family members and other caregivers to help coordinate care, understand health information, and make health care decisions. Accordingly, as part of these objectives, we encourage providers to provide access to health information to patient-authorized representatives in accordance with all applicable laws. We expect that patient-authorized representatives accessing such information under these objectives could include a wide variety of sources, including caregivers and various family members. However, we expect that patient-authorized representatives with access to such health information will always act on the patient’s behalf and in the patient’s best interests, and will remain free from any potential or actual conflict of interest with the patient. We further expect that the patient-authorized representatives would have the patient’s best interests at heart and will act in a manner protective of the patient.

(h) Discussion of the Relationship of Meaningful Use to CEHRT

We propose to continue our policy of linking each meaningful use objective to the CEHRT definition and to ONC-established certification criteria. As with Stage 1 and Stage 2, EPs, eligible hospitals, and CAHs must use technology certified to the certification criteria in the ONC Health IT Certification Program to meet the objectives and associated measures for Stage 3 of meaningful use. In some instances, meaningful use objectives and measures may not be directly enabled by certification criteria of the Health IT Certification Program. For example, in e-Rx and public health reporting, the CEHRT definition requires criteria established by the Health IT Certification Program to be applied to the message being sent or received and for purposes of message transmission. However, to actually

engage in e-Rx or public health reporting, there are many steps that must be taken to meet the requirements of the measure, such as contacting both parties and troubleshooting issues that may arise through the normal course of business. In these cases, the EP, eligible hospital, and CAH remain responsible for meeting the objectives and measures of meaningful use, but the way they do so is not entirely constrained by the CEHRT definition.

(i) Discussion of the Relationship Between a Stage 3 Meaningful Use Objective and Its Associated Measure

We propose to continue our Stage 1 and 2 policy that regardless of any actual or perceived gaps between the measure of an objective and full compliance with the objective, meeting the criteria of the measure means that the provider has met the objective for meaningful use in Stage 3.

Objective 1: Protect Patient Health Information

The Health Insurance Portability and Accountability Act (HIPAA) was enacted in part to provide federal protections for individually identifiable health information (IIHI). The Secretary of HHS adopted what are commonly known as the HIPAA Privacy, Security and Breach Notification Rules (HIPAA Rules) to implement certain aspects of the HIPAA statute and the HITECH statute pertaining to a patient’s IIHI. The Privacy Rule provides protections for most individually identifiable health information, in any form or media, whether electronic, paper, or oral, held by covered entities and business associates. The Security Rule specifies a series of administrative, physical, and technical standards that provide protections for most electronic individually identifiable health information, held by covered entities and business associates. Covered entities consist of most health care providers, health plans, and health care clearinghouses. Business associates consist of persons or organizations that perform certain functions or activities on behalf of, or provide certain services to, covered entities or other business associates that involve the use or disclosure of individually identifiable health information. Individually identifiable health information is information that relates to an individual’s physical or mental health or condition, the provision of health care to an individual, or the payment for the provision of health care to an individual. Individually identifiable health information is information that identifies an individual directly or with

respect to which there is a reasonable basis to believe it can be used to identify an individual. The individually identifiable health information protected by the HIPAA Rules is known as “protected health information” and that information in electronic form is known as “electronic protected health information” (ePHI). The Privacy Rule can be found at 45 CFR Part 160 and subparts A and E of part 164 and the Security Rule can be found at 45 CFR Part 160 and Subparts A and C of Part 164. Section 164.308(a)(1) of the Security Rule requires covered entities and business associates, among other things, to conduct a security risk analysis to assess the potential risks to the ePHI they create, receive, maintain, or transmit.

Consistent with HIPAA and its implementing regulations, and as we stated under both the Stage 1 and Stage 2 final rules (75 FR 44368 through 44369 and 77 FR 54002 through 54003), protecting ePHI remains essential to all aspects of meaningful use under the EHR Incentive Programs. We remain cognizant that unintended or unlawful disclosures of ePHI could diminish consumer confidence in EHRs and the overall exchange of ePHI. Therefore, in both the Stage 1 and 2 final rules, we created a meaningful use core objective aimed at protecting patients’ health care information. Most recently, we finalized at (77 FR 54002 and 54003), a Stage 2 meaningful use core objective requiring providers to “protect ePHI created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.” The measure for this objective requires providers to conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of data stored in CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implementing security updates as necessary, and correcting identified security deficiencies as part of the provider’s risk management process. For further detail on this objective, we refer readers to the Stage 2 proposed and final rules (77 FR 13716 through 13717 and 77 FR 54002).

In this Stage 3 proposed rule, we continue to emphasize the importance of protecting ePHI under the EHR Incentive Programs. With more and more users using electronic health records, we believe that adequate protection of ePHI remains instrumental to the continued success of the EHR Incentive Program.

However, public comments on the Stage 2 final rule and subsequent comments received through public forums, suggest some confusion remains among providers between the requirements of this meaningful use objective and the requirements established under 45 CFR 164.308(a)(1), 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3) of the HIPAA Security Rule. Although we stressed that the objective and measure finalized relating to ePHI are specific to the EHR Incentive Programs, and further added that compliance with the requirements in the HIPAA Security Rule falls outside the scope of this rulemaking, we nonetheless continued to receive inquiries about the relationship between our objective and the HIPAA Rules. Therefore, for Stage 3, in order to alleviate provider confusion and simplify the EHR Incentive Program, we are proposing to maintain the previously finalized Stage 2 objective on protecting ePHI. However, we propose further explanation of the security risk analysis timing and review requirements for purposes of meeting this objective and associated measure for Stage 3.

Proposed Objective: Protect electronic protected health information (ePHI) created or maintained by the certified EHR technology (CEHRT) through the implementation of appropriate technical, administrative, and physical safeguards.

For the proposed Stage 3 objective, we have added language to the security requirements for the implementation of appropriate technical, administrative, and physical safeguards. We propose to include administrative and physical safeguards because an entity would require technical, administrative, and physical safeguards to enable it to implement risk management security measures to reduce the risks and vulnerabilities identified. Technical safeguards alone are not enough to ensure the confidentiality, integrity, and availability of ePHI. Administrative safeguards (for example, risk analysis, risk management, training, and contingency plans) and physical safeguards (for example, facility access controls, workstation security) are also required to protect against threats and impermissible uses or disclosures to ePHI created or maintained by CEHRT.

Proposed Measure: Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data stored in CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR

164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider’s risk management process.

Under this proposed measure, a risk analysis must assess the risks and vulnerabilities to ePHI created or maintained by the CEHRT and must be conducted or reviewed for each EHR reporting period, which, as proposed in this rule, would be a full calendar year, and any security updates and deficiencies identified should be included in the provider’s risk management process and implemented or corrected as dictated by that process.

To address inquiries about the relationship between this measure and the HIPAA Security Rule, we explain that the requirement of this proposed measure is narrower than what is required to satisfy the security risk analysis requirement under 45 CFR 164.308(a)(1). The requirement of this proposed measure is limited to annually conducting or reviewing a security risk analysis to assess whether the technical, administrative, and physical safeguards and risk management strategies are sufficient to reduce the potential risks and vulnerabilities to the confidentiality, availability, and integrity of ePHI created by or maintained in CEHRT. In contrast, the security risk analysis requirement under 45 CFR 164.308(a)(1) must assess the potential risks and vulnerabilities to the confidentiality, availability, and integrity of all ePHI that an organization creates, receives, maintains, or transmits. This includes ePHI in all forms of electronic media, such as hard drives, floppy disks, CDs, DVDs, smart cards or other storage devices, personal digital assistants, transmission media, or portable electronic media.

We propose that the timing or review of the security risk analysis to satisfy this proposed measure must be as follows:

- EPs, eligible hospitals, and CAHs must conduct the security risk analysis upon installation of CEHRT or upon upgrade to a new Edition of certified EHR Technology. The initial security risk analysis and testing may occur prior to the beginning of the first EHR reporting period using that certified EHR technology.
- In subsequent years, a provider must review the security risk analysis of the CEHRT and the administrative, physical, and technical safeguards implemented, and make updates to its analysis as necessary, but at least once per EHR reporting period.

We note that providers have several resources available for strategies and

methods for securing ePHI. Completing a security risk analysis requires a time investment, and may necessitate the involvement of security, health IT, or system IT staff or support teams at your facility. The Office for Civil Rights (OCR) provides broad scale guidance on security risk analysis requirements at: <http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/rafinalguidancepdf.pdf>.

In addition, other tools and resources are available to assist providers in the process. For example, the Office of the National Coordinator for Health IT (ONC) provides guidance and a Security Risk Assessment (SRA) tool created in conjunction with OCR on its Web site at: <http://www.healthit.gov/providers-professionals/security-risk-assessment-tool>. The SRA Tool is a self-contained application available at no cost to the provider. There are a total of 156 questions and resources are included with each question to—

- Assist in understanding the context of the question
- Consider the potential impacts to ePHI if the requirement is not met
- See the actual safeguard language of the HIPAA Security Rule

In addition, the SRA Tool assists a provider by suggesting when corrective action may be required for a particular item. This tool is not required by the HIPAA Security Rule, but is one means by which providers and professionals in small and medium sized practices may perform a security risk analysis.

We further note that the 2015 Edition proposed rule published elsewhere in this issue of the **Federal Register** includes an auditable events and tamper-resistance criterion which is known as an “audit log” which can be a valuable resource in ensuring the protection of ePHI. While we recognize there may be legitimate instances where the function must be disabled for a short time, we strongly recommend providers ensure this function is enabled at all times when the CEHRT is in use. The audit log function serves to ensure consistent protection of ePHI as well as providing support in mitigating risk in other areas such as patient safety, adverse events, and in the event of any potential breach.

We emphasize that our discussion of this measure as it relates to 45 CFR 164.308(a)(1) is only relevant for purposes of the meaningful use requirements and is not intended to supersede or satisfy the broader, separate requirements under the HIPAA Security Rule and other rulemaking. Compliance with the requirements in the HIPAA Security Rule fall outside of the scope of this rulemaking.

Compliance with 42 CFR part 2 and state mental health privacy and confidentiality laws also fall outside the scope of this rulemaking. EPs, eligible hospitals, or CAHs affected by 42 CFR part 2 should consult with the Substance Abuse and Mental Health Services Administration (SAMHSA) or State authorities.

We welcome public comments on this proposal.

Objective 2: Electronic Prescribing

For Stage 3, we propose to maintain the objective and measure finalized in the Stage 2 final rule for electronic prescribing for EPs, with minor changes. In the Stage 2 final rule, we included for eligible hospitals and CAHs a menu set objective for the electronic prescription of discharge medications. We are proposing to include the Stage 2 menu objective, with a modification to increase the threshold, as a required objective for Stage 3 of meaningful use for eligible hospitals and CAHs.

For a full discussion of electronic prescribing as a meaningful use objective in the Stage 2 final rule, we direct readers to (77 FR 53989 through 53990 for EPs and 77 FR 54035 through 54036 for eligible hospitals and CAHs).

Proposed Objective: EPs must generate and transmit permissible prescriptions electronically, and eligible hospitals and CAHs must generate and transmit permissible discharge prescriptions electronically (eRx).

As discussed in the Stage 2 final rule (77 FR 53989), transmitting the prescription electronically promotes efficiency and patient safety through reduced communication errors. It also allows the pharmacy or a third party to automatically compare the medication order to others they have received for the patient that works in conjunction with clinical decision support interventions enabled at the generation of the prescription. While the EP performance rate across all years and stages of participation indicate wide spread adoption, with the median rate at 89 percent for Stage 1 and 92 percent for Stage 2³, we believe continued support of this objective is warranted to support the continued development of the ePrescribing marketplace. The continued expansion of the number and variety of products helps to reduce entry barriers and proliferate important standards for ePrescribing for a wide range of providers beyond those eligible for the EHR Incentive Programs. This

represents a benefit to patients and to population health through a potential overall reduction in the occurrence of prescription drug related adverse events. For eligible hospitals and CAHs, the performance rate among Stage 2 providers selecting the measure is higher than the 10 percent threshold and has increased since the previous report (median rate is 76⁴ percent). This opportunity to expand on early success, combined with the continued expansion of the pharmacy market acceptance of electronic prescriptions leads CMS to believe providers can meet an even higher threshold and should be encouraged to do so.

We propose to continue to define “prescription” as the authorization by a provider to dispense a drug that would not be dispensed without such authorization. This includes authorization for refills of previously authorized drugs. We propose to continue to generally define a “permissible prescription” as all drugs meeting the definition of prescription not listed as a controlled substance in Schedules II–V (DEA Web site at <http://www.deadiversion.usdoj.gov/schedules/index.html> (77 FR 53989) with a slight modification to allow for inclusion of scheduled drugs where such drugs are permissible to be electronically prescribed. We note that the electronic prescribing of controlled substances (EPCS) is now legal in many states. This functionality provides prescribers with a way to manage treatments for patients with pain electronically and also deters creation of fraudulent prescriptions, which is a major concern in combating opioid misuse and abuse. While the technology may, in many instances, be in place to support EPCS, workflow challenges and additional modifications may need to occur to meet the requirements of Drug Enforcement Agency regulations (75 FR 16236). However, as Stage 3 would not begin until January of 2017 and would not be required until January of 2018, it is possible that significant progress in the availability of products enabling the electronic prescribing of controlled substances may occur. Therefore, we are proposing that providers who practice in a state where controlled substances may be electronically prescribed who wish to include these prescriptions in the numerator and denominator may do so under the definition of “permissible prescriptions” for their practice. If a provider chooses to include such

³ Data may be found on the CMS Web site data and program reports page: <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>.

⁴ Data may be found on the CMS Web site data and program reports page: <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>.

prescriptions, they must do so uniformly across all patients and across all allowable schedules for the duration of the EHR reporting period.

For Stage 2, we requested comment on whether over-the-counter (OTC) medicines should be included in the definition of a prescription for this objective and determined that they should be excluded. For further information on that discussion, we direct readers to (77 FR 53989 and 53990). We maintain that OTC medicines will not be routinely electronically prescribed and propose to continue to exclude them from the definition of a prescription. However, we encourage public comment on this assumption and whether OTC medicines should be included in this objective for Stage 3.

In the Stage 2 final rule at (77 FR 53989), we discussed several different workflow scenarios that are possible when an EP prescribes a drug for a patient and that these differences in transmissions create differences in the need for standards. We propose to maintain this policy for Stage 3 for EPs and extend it to eligible hospitals and CAHs so that only a scenario in which a provider—

- Prescribes the drug;
- Transmits it to a pharmacy independent of the provider's organization; and
- The patient obtains the drug from that pharmacy requires the use of standards to ensure that the transmission meets the goals of electronic prescribing. In that situation, standards can ensure the whole process functions reliably. In all cases under this objective, the provider needs to use CEHRT as the sole means of creating the prescription, and when transmitting to an external pharmacy that is independent of the provider's organization, such transmission must be pursuant to ONC Health IT Certification Program criteria.

Proposed EP Measure: More than 80 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.

In Stage 1 of meaningful use, we adopted a measure of more than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using CEHRT. In the Stage 1 final rule (75 FR 44338), we acknowledged that there were reasons why a patient may prefer a paper prescription such as the desire to shop for the best price (especially for patients in the Part D “donut hole”), the indecision about whether to have the prescription filled locally or by mail

order, and the desire to use a manufacturer coupon (except in the Part D program) to obtain a discount.

In Stage 2, we adopted a measure of more than 50 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT. Our analysis of attestation data from Stages 1 and 2 shows that the median performance on this measure for Stage 1 EPs is 89 percent and for Stage 2 EPs is 92 percent, which demonstrates that the 50 percent threshold does not exceed the ceiling created by patient preferences⁵. We believe that with continued experience with this objective and the continued expansion of the pharmacy market acceptance of electronic prescriptions, providers can meet an even higher threshold and should be encouraged to do so in line with the statutory directive to seek to improve the use of EHRs and health care quality over time by requiring more stringent measures of meaningful use (see section 1848(o)(2)(A)(iii) of the Act). Therefore, we are proposing a threshold of 80 percent for this measure for Stage 3.

We propose to maintain for Stage 3 the exclusion from Stage 2 for EPs who write fewer than 100 permissible prescriptions during the EHR reporting period. We also propose to maintain for Stage 3 the exclusion from Stage 2 if no pharmacies within a 10-mile radius of an EP's practice location at the start of his or her EHR reporting period accept electronic prescriptions (77 FR 53990). This is 10 miles in any straight line from the practice location independent of the travel route from the practice location to the pharmacy. For EPs practicing at multiple locations, they are eligible for the exclusion if any of their practice locations equipped with CEHRT meet this criterion. An EP would not be eligible for this exclusion if he or she is part of an organization that owns or operates its own pharmacy within the 10-mile radius regardless of whether that pharmacy can accept electronic prescriptions from EPs outside of the organization.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

Denominator: Number of prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances during the EHR reporting period or Number of prescriptions written for drugs requiring

a prescription in order to be dispensed during the EHR reporting period.

Numerator: The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically using CEHRT.

Threshold: The resulting percentage must be more than 80 percent in order for an EP to meet this measure.

Exclusions: Any EP who: (1) Writes fewer than 100 permissible prescriptions during the EHR reporting period; or (2) does not have a pharmacy within their organization and there are no pharmacies that accept electronic prescriptions within 10 miles of the EP's practice location at the start of his or her EHR reporting period.

Proposed Eligible Hospital/CAH Measure: More than 25 percent of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT.

In the Stage 2 final rule, we included in this measure new, changed, and refill prescriptions ordered during the course of treatment of the patient while in the hospital (77 FR 54036). We are proposing to limit this measure for Stage 3 to only new and changed prescriptions. We believe this limitation is appropriate because prescriptions that originate prior to the hospital stay, and that remain unchanged, would be within the purview of the original prescriber, and not hospital staff or attending physicians. We propose to include this limitation as we believe that in most cases a hospital would not issue refills for medications that were not authorized or altered during a patient's hospital stay. With this new proposal, we invite public comment on whether a hospital would issue refills upon discharge for medications the patient was taking when they arrived at the hospital and, if so, whether distinguishing those refill prescriptions from new or altered prescriptions is unnecessarily burdensome for the hospital.

Our review of the Stage 2 attestation data for eligible hospitals and CAHs indicates performance levels of 53 percent at the median and 31 percent for the lowest quartile (www.cms.gov/ehrincentiveprograms Data and Reports). Thus, we are proposing to increase the threshold for the measure from 10 percent to 25 percent for Stage 3 of meaningful use for eligible hospitals and CAHs.

We propose to maintain the Stage 2 exclusion for any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic

⁵ Data can be found on the CMS Web site data and program reports page: <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>.

prescriptions and is not located within 10 miles of any pharmacy that accepts electronic prescriptions at the start of their EHR reporting period (77 FR 54036).

We recognize that not every patient will have a formulary that is relevant for him or her. If a relevant formulary is available, then the information can be provided. If there is no formulary for a given patient, the comparison could return a result of formulary unavailable for that patient and medication combination, and the provider may count the prescription in the numerator if they generate and transmit the prescription electronically as required by the measure.

To calculate the percentage, CMS and ONC have worked together to define the following for this objective:

Denominator: The number of new or changed prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances for patients discharged during the EHR reporting period.

Numerator: The number of prescriptions in the denominator generated, queried for a drug formulary and transmitted electronically.

Threshold: The resulting percentage must be more than 25 percent in order for an eligible hospital or CAH to meet this measure.

Exclusion: Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of their EHR reporting period.

We invite public comment on these proposals.

Objective 3: Clinical Decision Support

Proposed Objective: Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

Clinical decision support at the relevant point of care is an area of health IT in which significant evidence exists for substantial positive impact on the quality, safety, and efficiency of care delivery. For Stage 2, we finalized an objective for the use of CDS to improve performance on high-priority health conditions, and two associated measures (77 FR 53995 through 53998). The first measure requires a provider to implement five CDS interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period. Absent four CQMs related to the provider's scope of practice or patient population, the CDS interventions must be related to

high-priority health conditions. At least one of the CDS interventions should be related to improving healthcare efficiency. To meet the Stage 2 Clinical Decision Support objective, providers must implement the CDS intervention at a relevant point in patient care when the intervention can influence clinical decision making before an action is taken on behalf of the patient. Although we leave it to the provider's clinical discretion to determine the relevant point in patient care when such interventions will be most effective, the interventions must be presented through Certified EHR Technology to a licensed healthcare professional who can exercise clinical judgment about the decision support intervention before an action is taken on behalf of the patient. For the second measure, we consolidated the Stage 1 "drug-drug/drug-allergy interaction checks" objective into the Stage 2 CDS objective in the Stage 2 final rule (77 FR 53995 through 53998). The second measure requires a provider to enable and implement the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period. We also finalized an exclusion for the second measure for any EP who writes fewer than 100 medication orders during the EHR reporting period.

For Stage 3 of meaningful use, we propose to maintain the Stage 2 objective with slight modifications and further explanation of the relevant point of care, the types of CDS allowed, and the selection of a CDS applicable to a provider's scope of practice and patient population.

First, we offer further explanation of the concept of the relevant point of care and note that providers should implement the CDS intervention at a relevant point in clinical workflows when the intervention can influence clinical decision making before diagnostic or treatment action is taken in response to the intervention. Second, many providers may associate CDS with pop-up alerts; however, these alerts are not the only method of providing CDS. CDS should not be viewed as simply an interruptive alert, notification, or explicit care suggestion. Well-designed CDS encompasses a variety of workflow-optimized information tools, which can be presented to providers, clinical and support staff, patients, and other caregivers at various points in time. These may include but are not limited to: Computerized alerts and reminders for providers and patients; information displays or links; context-aware knowledge retrieval specifications which provide a standard mechanism to incorporate information from online

resources (commonly referred to as InfoButtons); clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support; and contextually relevant reference information. These functionalities may be deployed on a variety of platforms (that is, mobile, cloud-based, installed).⁶ We encourage innovative efforts to use CDS to improve care quality, efficiency, and outcomes. HIT functionality that builds upon the foundation of an EHR to provide persons involved in care processes with general and person-specific information, intelligently filtered and organized, at appropriate times, to enhance health and health care. CDS is not intended to replace clinician judgment, but rather, is a tool to assist care team members in making timely, informed, and higher quality decisions.

We propose to retain both measures of the Stage 2 objective for Stage 3 and we are proposing that these additional options mentioned previously on the actions, functions, and interventions may constitute CDS for purposes of meaningful use would meet the measure requirements outlined in the proposed measures.

Proposed Measures: EPs, eligible hospitals, and CAHs must satisfy both measures in order to meet the objective:

Measure 1: Implement five clinical decision support interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period. Absent four CQMs related to an EP, eligible hospital, or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions.

Measure 2: The EP, eligible hospital, or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

Exclusion: For the second measure, any EP who writes fewer than 100 medication orders during the EHR reporting period.

We recommend that providers explore a wide range of potential CDS interventions and determine the best mix for their practice and patient population. There are a wide range of CQMs which providers may implement in conjunction with the CDS. We refer readers to the CMS eCQM Library (www.cms.gov/ehrincentiveprograms/ecqmlibrary) for a list of the CQMs

⁶ FDASIA Health IT report available on the FDA Web site at: <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf>.

currently in use and under development for CMS programs and the associated National Quality Strategy domain categories.

In alignment with the HHS National Quality Strategy goals,⁷ providers are encouraged to implement CDS related to quality measurement and improvement goals on the following areas:

- Preventive care.
- Chronic condition management.
- Heart disease and hypertension.
- Appropriateness of diagnostic orders or procedures such as labs, diagnostic imaging, genetic testing, pharmacogenetic and pharmacogenomic test result support or other diagnostic testing.
- Advanced medication-related decision support, to include pharmacogenetic and pharmacogenomic test result support.

An example of a potential CDS a provider may include which highlights the proposed expansion of the variety of workflow-optimized tools available for providers, and the link between a CDS and a high priority health condition, may be found in the use of treatment protocols and algorithms within the Million Hearts initiative. The Million Hearts initiative emphasizes the use of treatment protocols which can be embedded throughout the clinical workflow for hypertension control to standardize a team's or system's approach to achieving outcomes of interest. These treatment protocols or algorithms can expand the number of care team members that can assist in achieving desired outcomes; lend clarity, efficiency, and cost-effectiveness to selection of medications; and specify intervals and processes for patient follow up for care related to hypertension. For further information on this example, we direct readers to the Million Hearts initiative protocols <http://millionhearts.hhs.gov/resources/protocols.html>. In this example, these CDS interventions are applied to utilize standardized treatment approaches or protocols specific to hypertension control; however, we emphasize that similar strategies and approaches to the implementation of a variety of CDS can be widely applied. Another relevant example is clinical decision support in certified EHR technology that is used for consultation regarding appropriate use criteria for applicable imaging services as outlined in section 218 of the "Protecting Access to Medicare Act of 2014" which includes provisions focused on promoting evidence based

care. We welcome public comments on the proposals.

As in the Stage 2 final rule (77 FR 53997), we do not propose to require the provider to report a change in performance on individual CQMs either independently or in relation to the paired CDS. Rather, we recommend each provider set internal goals for improved performance using the CQM, or related set of CQMs, as indicators for their own reference when selecting and implementing a CDS intervention. We note that for CDS and CQM pairings, we recommend providers focus on the use of CQMs which measure patient outcomes (also known as outcome measures), as preferred over CQMs which measure clinical process without consideration of a particular outcome (also known as process measures). Outcome measure CQMs are designed to provide a patient-centered and outcome-focused indicator for quality improvement goal-setting and planning. Where possible, we recommend providers implement CDS interventions which relate to care quality improvement goals and a related outcome measure CQM. However, for specialty hospitals and certain EPs, if there are no CQMs which are outcome measures related to their scope of practice, the provider should implement a CDS intervention related to a CQM process measure; or if none of the available CQMs apply, the provider should apply an intervention that he or she believes will be effective in improving the quality, safety, or efficiency of patient care.

CMS and ONC are committed to harmonizing the quality improvement ecosystem, refining and developing outcome measures, and aligning standards for CDS and quality measurement. Work is underway in the ONC Standards and Interoperability Framework to align and develop a shared quality improvement data model and technical expression standards for both CDS and quality measurement. Upon successful completion, such standards may be considered for inclusion in future quality measurement and certification rulemaking.

Given the wide range of CDS interventions currently available and the continuing development of new technologies, we do not believe that any EP, eligible hospital, or CAH would be unable to identify and implement five CDS interventions as previously described. Therefore, we do not propose any exclusion for the first measure of this objective.

Objective 4: Computerized Provider Order Entry

In the Stage 2 final rule, we expanded the use of computerized provider order entry (CPOE) from the Stage 1 objective requiring only medication orders to be entered using CPOE to include laboratory orders and radiology orders. For a full discussion of this expansion, we direct readers to (77 FR 53985 through 53989). We maintain CPOE continues to represent an opportunity for providers to leverage technology to capture these orders to reduce error and maximize efficiencies within their practice, therefore we are proposing to maintain the use of CPOE for these orders as an objective of meaningful use for Stage 3.

Proposed Objective: Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.

We propose to continue to define CPOE as the provider's use of computer assistance to directly enter clinical orders (for example, medications, consultations with other providers, laboratory services, imaging studies, and other auxiliary services) from a computer or mobile device. The order is then documented or captured in a digital, structured, and computable format for use in improving safety and efficiency of the ordering process.

We propose to continue our policy from the Stage 2 final rule that the orders to be included in this objective are medication, laboratory, and radiology orders as such orders are commonly included in CPOE implementation and offer opportunity to maximize efficiencies for providers. However, for Stage 3, we are proposing to expand the objective to include diagnostic imaging, which is a broader category including other imaging tests such as ultrasound, magnetic resonance, and computed tomography in addition to traditional radiology. This change addresses the needs of specialists and allows for a wider variety of clinical orders relevant to particular specialists to be included for purposes of measurement.

In Stage 3, we propose to continue the policy from the Stage 2 final rule at 77 FR 53986 that orders entered by any licensed healthcare professional or credentialed medical assistant would

⁷ HHS National Quality Strategy: <http://www.ahrq.gov/workingforquality/>.

count toward this objective. A credentialed medical assistant may enter orders if they are credentialed to perform the duties of a medical assistant by a credentialing body other than the employer. If a staff member of the eligible provider is appropriately credentialed and performs assistive services similar to a medical assistant, but carries a more specific title due to either specialization of their duties or to the specialty of the medical professional they assist, orders entered by that staff member would be included in this objective. We further note that medical staff whose organizational or job title, or the title of their credential, is other than medical assistant may enter orders if these staff are credentialed to perform the equivalent duties of a credentialed medical assistant by a credentialing body other than their employer and perform such duties as part of their organizational or job title. We defer to the provider's discretion to determine the appropriateness of the credentialing of staff to ensure that any staff entering orders have the clinical training and knowledge required to enter orders for CPOE. This determination must be made by the EP or representative of the eligible hospital or CAH based on—

- Organizational workflows;
- Appropriate credentialing of the staff member by an organization other than the employing organization;
- Analysis of duties performed by the staff member in question; and
- Compliance with all applicable federal, state, and local laws and professional guidelines.

However, as stated in the Stage 2 final rule at 77 FR 53986, it is apparent that the prevalent time when CDS interventions are presented is when the order is entered into CEHRT, and that not all EHRs also present CDS when the order is authorized (assuming such a multiple step ordering process is in place). This means that the person entering the order would be required to enter the order correctly, evaluate a CDS intervention either using their own judgment or through accurate relay of the information to the ordering provider, and then either make a change to the order based on the information provided by the CDS intervention or bypass the intervention. The execution of this role represents a significant impact on patient safety; therefore, we continue to maintain for Stage 3 that a layperson is not qualified to perform these tasks. We believe that the order must be entered by a qualified individual. We further propose that if the individual entering the orders is not the licensed healthcare professional, the order must be entered with the direct

supervision or active engagement of a licensed healthcare professional.

We propose to maintain for Stage 3 our existing policy for Stages 1 and 2 that the CPOE function should be used the first time the order becomes part of the patient's medical record and before any action can be taken on the order. The numerator of this objective also includes orders entered using CPOE initially when the patient record became part of the certified EHR. This does not include paper orders entered initially into the patient record and then transferred to CEHRT by other individuals at a later time, nor does it include orders entered into technology not compliant with the CEHRT definition and transferred into the CEHRT at a later time. In addition, based on the discussion in the Stage 2 final rule (77 FR 53986), we propose to maintain for Stage 3 that "protocol" or "standing" orders may be excluded from this objective. The defining characteristic of these orders is that they are not created due to a specific clinical determination by the ordering provider for a given patient, but rather are predetermined for patients with a given set of characteristics (for example, administer medication X and order lab Y for all patients undergoing a certain specific procedure or refills for given medication). We agree that this category of orders warrant different considerations than orders that are due to a specific clinical determination by the ordering provider for a specific patient. Therefore, we allow providers to exclude orders that are predetermined for a given set of patient characteristics or for a given procedure from the calculation of CPOE numerators and denominators. However, the exclusion of this type of order may not be a blanket policy for patients presenting with a specific diagnosis or symptom which requires the evaluation and determination of the provider for the order.

We propose to maintain the Stage 2 description of "laboratory services" as any service provided by a laboratory that could not be provided by a non-laboratory for the CPOE objective for Stage 3 (77 FR 53984). We also propose to maintain for Stage 3 the Stage 2 description of "radiologic services" as any imaging service that uses electronic product radiation (77 FR 53986). Even though we are proposing to expand the CPOE objective from radiology orders to all diagnostic imaging orders, this description would still apply for radiology services within the expanded objective.

We invite public comment on these proposals.

Proposed Measures: An EP, eligible hospital or CAH must meet all three measures.

Proposed Measure 1: More than 80 percent of medication orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry;

Proposed Measure 2: More than 60 percent of laboratory orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry; and

Proposed Measure 3: More than 60 percent of diagnostic imaging orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

We propose to continue a separate percentage threshold for all three types of orders: medication, laboratory, and diagnostic imaging. We continue to believe that an aggregate denominator cannot best capture differentiated performance on the individual order types within the objective, and therefore maintain a separate denominator for each order type. We propose to retain exclusionary criteria from Stage 2 for those EPs who so infrequently issue an order type specified by the measures (write fewer than 100 of the type of order), that it is not practical to implement CPOE for that order type.

Based on our review of attestation data from Stages 1 and 2 demonstrating provider performance on the CPOE measures, we propose to increase the threshold for medication orders to 80 percent and to increase the threshold for diagnostic imaging orders and laboratory orders to 60 percent. Median performance for Stage 1 on medication orders is 95 percent for EPs and 93 percent for eligible hospitals and CAHs. Stage 2 median performance on laboratory and radiology orders is 80 percent and 83 percent for eligible hospitals and CAHs and 100 percent for EPs for both measures.⁸ We believe it is reasonable to expect the actual use of CPOE for medication orders to increase from 60 percent in Stage 2 to 80 percent in Stage 3 and the actual use of CPOE for diagnostic imaging and laboratory

⁸Data can be found on the CMS Web site data and program reports page: <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>.

orders to increase from 30 percent in Stage 2 to 60 percent in Stage 3. We note that despite the expansion of the category for radiology orders to diagnostic imaging orders, we do not anticipate a negative impact on the ability of providers to meet the higher threshold as the adoption of the expanded functionality does not require additional workflow implementation and allows for inclusion of a wider range of orders already being captured by many providers. Therefore, for medication orders we propose the threshold at 80 percent and for diagnostic imaging and laboratory orders we propose the threshold at 60 percent for Stage 3.

In the Stage 2 final rule, we addressed the concern posed when calculating a denominator of all orders entered into the CEHRT while limiting the numerator to only those entered into CEHRT using CPOE (77 FR 53987 through 53988). Potentially, this would exclude those orders that are never entered into the CEHRT in any manner. The provider would be responsible for including those orders in their denominator. However, we believe that providers using CEHRT use it as the patient's medical record; therefore, an order not entered into CEHRT would be an order that is not entered into a patient's medical record. For this reason, we expect that orders given for patients that are never entered into the CEHRT to be few in number or non-existent. While our experience with both Stage 1 and Stage 2 of meaningful use has shown that a denominator of all orders created by the EP or in the hospital would not be unduly burdensome for providers and would create a better measurement for CPOE usage, particularly for EPs who infrequently order medications, this does not guarantee such a denominator would be feasible for all providers. We invite comments on whether to continue to allow, but not require, providers to limit the measure of this objective to those patients whose records are maintained using CEHRT.

Proposed Measure 1: To calculate the percentage, CMS and ONC have worked together to define the following for this measure:

Denominator: Number of medication orders created by the EP or authorized providers in the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of orders in the denominator recorded using CPOE.

Threshold: The resulting percentage must be more than 80 percent in order

for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP who writes fewer than 100 medication orders during the EHR reporting period.

Proposed Measure 2: To calculate the percentage, CMS and ONC have worked together to define the following for this measure:

Denominator: Number of laboratory orders created by the EP or authorized providers in the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of orders in the denominator recorded using CPOE.

Threshold: The resulting percentage must be more than 60 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP who writes fewer than 100 laboratory orders during the EHR reporting period.

Proposed Measure 3: To calculate the percentage, CMS and ONC have worked together to define the following for this measure:

Denominator: Number of diagnostic imaging orders created by the EP or authorized providers in the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of orders in the denominator recorded using CPOE.

Threshold: The resulting percentage must be more than 60 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP who writes fewer than 100 diagnostic imaging orders during the EHR reporting period.

We seek comment on if there are circumstances which might warrant an additional exclusion for an EP such as a situation representing a barrier to successfully implementing the technology required to meet the objective. We also seek comment on if there are circumstances where an eligible hospital or CAH which focuses on a particular patient population or specialty may have an EHR reporting period where the calculation results in a zero denominator for one of the measures, how often such circumstances might occur, and whether an exclusion would be appropriate.

An EP through a combination of meeting the thresholds and exclusions must satisfy all three measures for this objective. An eligible hospital or CAH must meet the thresholds for all three measures.

We welcome public comment on these proposals.

Objective 5: Patient Electronic Access to Health Information

The Stage 1 and Stage 2 final rules included a number of objectives focused on increasing patient access to health information and supporting provider and patient communication. These objectives include patient reminders (77 FR 54005 through 54007), patient-specific education resources (77 FR 54011 through 54012), clinical summaries of office visits (77 FR 53998 through 54002), secure messaging (77 FR 54031 through 54033), and the ability for patients to view, download, and transmit their health information to a third party (77 FR 54007 through 54011). For Stage 3, we generally identified two related policy goals within the overall larger goal of improved patient access to health information and patient-centered communication. The first is to ensure patients have timely access to their full health record and related important health information; and the second is to engage in patient-centered communication for care planning and care coordination. While these two goals are intricately linked, we see them as two distinct priorities requiring different foci and measures of success. For the first goal, we are proposing to incorporate the Stage 2 objectives related to providing patients with access to health information, including the objective for providing access for patients (or their authorized representatives) to view online, download, and transmit their health information and the objective for patient-specific education resources, into a new Stage 3 objective entitled, "Patient Electronic Access" (Objective 5), focused on using certified EHR technology to support increasing patient access to important health information. For the second goal, we are proposing an objective entitled Coordination of Care through Patient Engagement (Objective 6) incorporating the policy goals of the Stage 2 objectives related to secure messaging, patient reminders, and the ability for patients (or their authorized representatives) to view online, download, and transmit their health information using the functionality of the certified EHR technology.

In this Stage 3 Patient Electronic Access Objective, we are proposing to incorporate certain measures and objectives from Stage 2 into a single objective focused on providing patients with timely access to information related to their care. This proposed objective is a consolidation of the first measure of the Stage 2 Core Objective

for EPs of “Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP” and the Stage 2 Core Objective for EPs to “Use clinically relevant information from CEHRT to identify patient-specific education resources and provide those resources to the patient.” For eligible hospitals and CAHs, this proposed objective consolidates the first measure of the Stage 2 Core Objective for eligible hospitals/CAHs of “Provide patients the ability to view online, download, and transmit information about a hospital admission” and the Stage 2 Core Objective “Use clinically relevant information from CEHRT to identify patient-specific education resources and provide those resources to the patient.” For further discussion around the development of the Stage 2 objectives, we direct readers to the Stage 2 final rule at (77 FR 53973).

In Stage 2, there are objectives that allow providers to communicate and provide information to patients through paper-based means, such as clinical summaries of office visits and patient-specific education resources. Although these methods of communication and information exchange are embraced by many providers and patients and we continue to support their use, we will no longer require or allow providers to capture and calculate these actions or attest to these measures for meaningful use Stage 3. While we believe that providing patients access to health information in many formats is beneficial to patient-centered communication, care delivery, and quality improvement, meaningful use Stage 3 focuses exclusively on electronic, certified EHR technology supported communication.

We are also proposing to expand the options through which providers may engage with patients under the EHR Incentive Programs. Specifically, we are proposing an additional functionality, known as application-program interfaces (APIs), which would allow providers to enable new functionalities to support data access and patient exchange. An API is a set of programming protocols established for multiple purposes. APIs may be enabled by a provider or provider organization to provide the patient with access to their health information through a third-party application with more flexibility than often found in many current “patient portals.” From the provider perspective, using this option would mean the provider would not be required to separately purchase or implement a “patient portal,” nor

would they need to implement or purchase a separate mechanism to provide the secure download and transmit functions for their patients because the API would provide the patient the ability to download or transmit their health information to a third party. If the provider elects to implement an API, the provider would only need to fully enable the API functionality, provide patients with detailed instructions on how to authenticate, and provide supplemental information on available applications which leverage the API. For further discussion on the technical requirements for APIs, we direct readers to the 2015 Edition proposed rule published elsewhere in this issue of the **Federal Register**. The certification criteria proposed by ONC would establish API criteria which would allow patients, through a third-party application, to pull certain components of their unique health data directly from the provider’s CEHRT, and potentially could—on demand—pull such information from multiple providers caring for a patient. Therefore, we are proposing for the Patient Electronic Access objective to allow providers to enable API functionality in accordance with the proposed ONC requirements in the 2015 Edition proposed rule published elsewhere in this issue of the **Federal Register**.

From the patient perspective, an API enabled by a provider will empower the patient to receive information from their provider in the manner that is most valuable to that particular patient. Patients would be able to collect their health information from multiple providers and potentially incorporate all of their health information into a single portal, application, program, or other software. We also believe that provider-enabled APIs allow patients to control the manner in which they receive their health information while still ensuring the interoperability of data across platforms. In addition, we recognize that a large number of patients consult with and rely on trusted family members and other caregivers to help coordinate care, understand health information, and make decisions. Therefore, we encourage providers to provide access to health information to appropriately authorized patient representatives.

As some low-cost and free API functions already exist in the health IT industry, we expect third-party application developers to continue to create low-cost solutions that leverage APIs as part of their business models. Therefore, we encourage health IT system developers to leverage these existing API platforms and applications

to allow providers no-cost, or low-cost solutions to implement and enable an API as part of their CEHRT systems. In addition, we do not believe it would be appropriate for EPs and hospitals to charge patients a fee for accessing their information using an API.

The goal of this objective is to allow patients easy access to their health information as soon as possible, so that they can make informed decisions regarding their care and share their most recent clinical information with other health care providers and personal caregivers as they see fit. We believe this is also integral to the Hospital Partnership for Patients initiative and reducing hospital readmissions. This objective aligns with the Fair Information Practice Principles (FIPPs),⁹ in affording baseline privacy protections to individuals.¹⁰

We seek comment on what additional requirements might be needed to ensure that if the eligible hospital, CAH or EP selects the API option—(1) the functionality supports a patient’s right to have his or her protected health information sent directly to a third party designated by the patient; and (2) patients have at least the same access to and use of their health information that they have under the view, download, and transmit option.

Proposed Objective: The EP, eligible hospital, or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability.

We continue to believe that patient access to their electronic health

⁹ 1 In 1973, the Department of Health, Education, and Welfare (HEW) released its report, *Records, Computers, and the Rights of Citizens*, which outlined a Code of Fair Information Practices that would create “safeguard requirements” for certain “automated personal data systems” maintained by the Federal Government. This Code of Fair Information Practices is now commonly referred to as fair information practice principles (FIPPs) and established the framework on which much privacy policy would be built. There are many versions of the FIPPs; the principles described here are discussed in more detail in *The Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information*, December 15, 2008. http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_privacy_security_framework/1173.

¹⁰ The FIPPs, developed in the United States nearly 40 years ago, are well-established and have been incorporated into both the privacy laws of many states with regard to government-held records and numerous international frameworks, including the development of the OECD’s privacy guidelines, the European Union Data Protection Directive, and the Asia-Pacific Economic Cooperation (APEC) Privacy Framework. http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_privacy_security_framework/1173.

information is a high priority for the EHR Incentive Programs. Furthermore, providing educational resources about a patient's health including recommendations for preventative care and screenings, identifying risk factors, and other important health resources can help to increase patient health literacy, empower patients to make more informed decisions, and support the efforts of providers in managing a patient care plan. We also believe that patient access to health information should be provided in the manner requested by the patient when possible.

We note that for this objective, the provider is only required to provide access to the information through these means; the patient is not required to take action in order for the provider to meet this objective. In the Patient Electronic Access to Health Information objective, we note that "provides access" means that the patient has all the tools they need to gain access to their health information including any necessary instructions, user identification information, or the steps required to access their information if they have previously elected to "opt-out" of electronic access. If this information is provided to the patient in a clear and actionable manner, the provider may count the patient for this objective. Additionally, this objective should not require the provider to make extraordinary efforts to assist patients in use or access of the information, but the provider must inform patients of these options, and provide sufficient guidance so that all patients could leverage this access. The providers may withhold from online disclosure any information either prohibited by federal, state, or local laws or if such information provided through online means may result in significant harm. We also note, as we have previously, that this is a meaningful use requirement, which does not affect an individual's right under HIPAA to access his or her health information. Providers must continue to comply with all applicable requirements under the HIPAA Privacy Rule, including the access provisions of 45 CFR 164.524.

Proposed Measures: EPs, eligible hospitals, and CAHs must satisfy both measures in order to meet the objective:

Proposed Measure 1: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

(1) The patient (or patient-authorized representative) is provided access to view online, download, and transmit their health information within 24 hours of its availability to the provider; or

(2) The patient (or patient-authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient-authorized representatives) access to their health information, within 24 hours of its availability to the provider.

Proposed Measure 2: The EP, eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

We propose that for measure 1, the patient must be able to access this information on demand, such as through a patient portal, personal health record (PHR), or API and have everything necessary to access the information even if they opt out. All three functionalities (view, download, and transmit) or an API must be present and accessible to meet the measure. The functionality must support a patient's right to have his or her protected health information sent directly to a third party designated by the patient consistent with the provision of access requirements at 45 CFR 164.524(c) of the HIPAA Privacy Rule.

However, if the provider can demonstrate that at least one application that leverages the API is available (preferably at no cost to the patient) and that more than 80 percent of all unique patients have been provided instructions on how to access the information; the provider need not create, purchase, or implement redundant software to enable view, download, and transmit capability independently of the API.

We propose to increase the threshold for measure 1 from the Stage 1 and Stage 2 threshold of 50 percent to a threshold of 80 percent for Stage 3. We believe that all patients should be provided access to their electronic health record; however, we are setting the threshold at 80 percent based on the highest threshold defined for measures based on unique patients seen by the provider during the EHR reporting period in the Stage 2 final rule (for example see 77 FR 53993). Based on the continued progress toward automation and standardization of data capture supported by CEHRT which facilitates a faster response time, we further propose to decrease patient wait time for the availability of information to within 24 hours of the office visit or of the information becoming available to the provider for

potential inclusion in the case of lab or other test results which require sufficient time for processing and returning results.

For measure 2, we propose to increase the threshold that was finalized in Stage 2 from 10 percent to 35 percent. We believe that the 35 percent threshold both ensures that providers are using CEHRT to identify patient-specific education resources and is low enough to not infringe on the provider's freedom to choose education resources and to which patients these resources will be provided.

We continue to propose that both measures for this objective must be met using CEHRT. For the purposes of meeting this objective, this would mean the capabilities provided by a patient portal, PHR, or any other means of online access that would permit a patient or authorized representatives to view, download, and transmit their personal health information and/or any API enabled, must be certified in accordance with the certification requirements adopted by ONC.

We are proposing a continuation of the exclusion in Stage 2 for both EPs and eligible hospitals/CAHs in that any EP, eligible hospital, or CAH would be excluded from the first measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period. We continue to recognize that in areas of the country where a significant section of the patient population does not have access to broadband internet, this measure may be significantly harder or impossible to achieve. Finally, we propose an additional exclusion for EPs for Stage 3, that any EP who has no office visits during the EHR reporting period may be excluded from the measures. We encourage comments on these exclusions and will evaluate them again in light of the public comments received.

Proposed Measure 1: To calculate the percentage, CMS and ONC have worked together to define the following for this measure:

Denominator: The number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of patients in the denominator who are provided access to information within 24 hours of its availability to the EP or eligible hospital/CAH.

Threshold: The resulting percentage must be more than 80 percent in order for a provider to meet this measure.

Exclusions: An EP may exclude from the measure if they have no office visits during the EHR reporting period.

Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the measure.

Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Proposed Measure 2: To calculate the percentage, CMS and ONC have worked together to define the following for this measure:

Denominator: The number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of patients in the denominator who were provided electronic access to patient-specific educational resources using clinically relevant information identified from CEHRT.

Threshold: The resulting percentage must be more than 35 percent in order for a provider to meet this measure.

Exclusions: An EP may exclude from the measure if they have no office visits during the EHR reporting period.

Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the measure.

Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Alternate Proposals:

We note that for measure one we are seeking comment on the following set of alternate proposals for providers to meet the measure using the functions of CEHRT outlined previously in this section. These alternate proposals

involve the requirements to use a view, download, and transmit function or an API to provide patients access to their health information. We believe the current view, download, and transmit functions are widely in use and represent the current standard for patient access to their health record. However, we believe that the use of APIs could potentially replace this function and move toward a more accessible means for patients to access their information. Therefore, we are seeking comment on alternatives which would present a different mix of CEHRT functionality for providers to use for patients seeking to access their records. The proposed first measure discussed previously would allow providers the option either to give patients access to the view, download, and transmit functionality, or to give patients access to an API. Specifically, we are seeking comment on whether the API option should be required rather than optional for providers, and if so, should providers also be required to offer the view, download, and transmit function.

Proposed Measure 1: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

(1) The patient (or patient-authorized representative) is provided access to view online, download, and transmit their health information within 24 hours of its availability to the provider; or

(2) The patient (or the patient-authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient authorized representatives) access to their health information, within 24 hours of its availability to the provider.

Alternate A: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23):

(1) The patient (or the patient-authorized representative) is provided access to view online, download, and transmit his or her health information within 24 hours of its availability to the provider; and

(2) The patient (or patient-authorized representatives) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient authorized representatives) access to their health information within 24 hours of its availability to the provider.

Alternate B: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or

CAH inpatient or emergency department (POS 21 or 23):

(1) The patient (or patient-authorized representative) is provided access to view online, download, and transmit their health information within 24 hours of its availability to the provider; and the patient (or patient-authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient authorized representatives) access to their health information within 24 hours of its availability to the provider; or,

(2) The patient (or patient-authorized representatives) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient authorized representatives) access to their health information within 24 hours of its availability to the provider.

Alternate C: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), the patient (or patient-authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient-authorized representatives) access to their health information, within 24 hours of its availability to the provider.

These three alternate proposals would represent different use cases for the CEHRT function to support view, download, and transmit and/or API functionality. We note that under these proposed alternates the following mix of functions would be applicable: Alternate A would require both functions to be available instead of allowing the provider to choose between the two; Alternate B would require the provider to choose to have either both functions, or just an API function; and Alternate C would require the provider to only have the API function. For Alternate C, the use of a separate view, download, and transmit function would be entirely at the provider's discretion and not included as part of the definition of meaningful use.

We welcome public comment on these proposals.

Objective 6: Coordination of Care Through Patient Engagement

As mentioned previously, the Stage 1 and Stage 2 final rules included a number of objectives focused on patient access to health information and communication among providers, care teams, and patients. These patient engagement objectives focused on changing behaviors among providers and patients to promote patient

involvement in health care. Specifically, the objectives included supporting provider and patient communication about their health, improving overall patient health literacy, and supporting patient-driven coordination with providers and other members of the patient's care team. The Stage 1 and Stage 2 objectives included patient reminders (77 FR 54005 through 54007), patient-specific education resources (77 FR 54011 through 54012), clinical summaries of office visits (77 FR 53998 through 54002), secure messaging (77 FR 54031 through 54033), and the ability for patients to view, download, and transmit their health information to a third party (77 FR 54007 through 54011). For Stage 3, as mentioned previously, we are proposing to incorporate the Stage 2 objectives related to providing patients with access to health information into a new Stage 3 objective entitled, "Patient Electronic Access" (Objective 5). For the proposed objective entitled Coordination of Care through Patient Engagement (Objective 6), we are proposing to incorporate the policy goals of the Stage 2 objectives related to secure messaging, patient reminders, and the measure of patient engagement requiring patients (or their authorized representatives) to view, download, and transmit their health information using the functionality of the certified EHR technology.

As mentioned previously, while we believe there may be many methods of communication and information sharing among providers, or other care team members, and patients (including paper-based or telephone communications), meaningful use Stage 3 focuses exclusively on electronic, certified EHR technology supported communication in the requirements outlined in this proposed objective for Coordination of Care through Patient Engagement.

Proposed Objective: Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.

Specifically, this proposed rule focuses on encouraging the use of EHR functionality for secure dialogue and efficient communication between providers, care team members, and patients about their care and health status, as well as important health information such as preventative and coordinated care planning. In addition, certified EHR technology functions designed to support patient engagement can be a platform to securely capture and record patient-generated health data and information provided in non-clinical care settings.

We are also proposing to expand the options through which providers may engage with patients under the EHR Incentive Programs including the use of APIs as mentioned previously. An API can enable a patient—through a third-party application—to access and retrieve their health information from a care provider in a way that is most valuable to that particular patient.

Therefore, we are proposing a meaningful use objective for Stage 3 to support this provider and patient engagement continuum based on the foundation already created within the EHR Incentive Programs but using new methods and expanded options to advance meaningful patient engagement and patient-centered care. We also propose that for purposes of this objective, patient engagement may include patient-centered communication between and among providers facilitated by authorized representatives of the patient and of the EP, eligible hospital, or CAH. As care delivery evolves, the participation of a diverse group of care team members enables more robust care for the patient. Engagement between the patient and, for example, nutritionists, social workers, physical therapists, or other members of the provider's care team is crucial to effective patient engagement and are therefore included in this objective.

For Stage 3 of meaningful use, we propose the following measures for the Patient Engagement Objective:

Proposed Measures: We are proposing that providers must attest to the numerator and denominator for all three measures, but would only be required to successfully meet the threshold for two of the three proposed measures to meet the Coordination of Care through Patient Engagement Objective. These three measures support the communication continuum between providers, patients, and the patient's authorized representatives through the use of view, download, and transmit functionality. They also support using API functionality through patient engagement with their health data, but also potentially through secure messaging functions and standards, and the capture and inclusion of data collected from non-clinical settings, including patient-generated health data.

Proposed Measure 1: During the EHR reporting period, more than 25 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the electronic health record made accessible by the provider. An EP, eligible hospital or CAH may meet the measure by either:

(1) More than 25 percent of all unique patients (or patient-authorized representatives) seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period view, download or transmit to a third party their health information; or

(2) More than 25 percent of all unique patients (or patient-authorized representatives) seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period access their health information through the use of an ONC-certified API that can be used by third-party applications or devices.

Proposed Measure 2: For more than 35 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or the patient's authorized representatives), or in response to a secure message sent by the patient (or the patient's authorized representative).

Proposed Measure 3: Patient-generated health data or data from a non-clinical setting is incorporated into the certified EHR technology for more than 15 percent of all unique patients seen by the EP or discharged by the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

For measure 1, we are proposing to increase the threshold for the measure from 5 percent to 25 percent based on provider performance on the related Stage 2 measure requiring more than 5 percent of patients to view, download, or transmit to a third party the health information made available to them by the provider. Stage 2 median performance for an EP on this measure is 32 percent and 11 percent for eligible hospitals.¹¹ Therefore, we are proposing more than 25 percent of all unique patients (or the patient's authorized representatives) seen by the EP, eligible hospital or CAH during the EHR reporting period must view, download, or transmit to a third party their health information or access their health information through the use of an ONC-certified API that can be used by third-party applications or devices. For the API option, we propose that providers must attest that they have enabled an API and that at least one application

¹¹ Data can be found on CMS Web site Data and Program Reports page: <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>.

which leverages the API is available to patients (or the patient-authorized representatives) to retrieve health information from the provider's certified EHR.

CMS recognizes that there may be inherent challenges in measuring patient access to CEHRT through third-party applications that utilize an ONC-certified API, and we solicit comment on the nature of those challenges and what solutions can be put in place to overcome them. For example, are there specific requirements around the use of APIs or are there specific certification requirements for APIs that could make the measurement of this objective easier. We also solicit comment on suggested alternate proposals for measuring patient access to CEHRT through third-party applications that utilize an API, including the pros and cons of measuring a minimum number of patients (one or more) who must access their health information through the use of an API in order to meet the measure of this objective.

For measure 2, the EP, eligible hospital, CAH, or the provider's authorized representative must communicate with the patient (or the patient's authorized representatives), through secure electronic messaging for more than 35 percent of the unique patients seen by the provider during the EHR reporting period. "Communicate" means when a provider sends a message to a patient (or the patient's authorized representatives) or when a patient (or the patient's authorized representatives) sends a message to the provider. In patient-to-provider communication, the provider must respond to the patient (or the patient's authorized representatives) for purposes of this measure. We propose to increase the threshold for this measure over the threshold for the Stage 2 measure because for Stage 3 provider initiated messages would count toward the measure numerator.

For measure 2, we propose to include in the measure numerator situations where providers communicate with other care team members using the secure messaging function of certified EHR technology, and the patient is engaged in the message and has the ability to be an active participant in the conversation between care providers. However, we seek comment on how this action could be counted in the numerator, and the extent to which that interaction could or should be counted for eligible providers engaged in the communication. For example, should only the initiating provider be allowed to include the communication as an action in the numerator? Or, should any provider who contributes to such a

message during the EHR reporting period be allowed to count the communication? In addition, we seek comment on what should be considered a contribution to the patient-centered communication; for example, a contribution must be active participation or response, a contribution may be viewing the communication, or a contribution may be simple inclusion in the communication.

We specify that the secure messages sent should contain relevant health information specific to the patient in order to meet the measure of this objective. We believe the provider is the best judge of what health information should be considered relevant in this context. For the purposes of this measure, we are proposing that secure messaging content may include, but is not limited to, questions about test results, problems, and medications; suggestions for follow-up care or preventative screenings; confirmations of diagnosis and care plan goals; and information regarding patient progress. However, we note that messages with content exclusively relating to billing questions, appointment scheduling, or other administrative subjects should not be included in the numerator. For care team secure messaging with the patient included in the conversation, we also believe the provider may exercise discretion if further communications resulting from the initial action should be excluded from patient disclosure to prevent harm. We note that if such a message is excluded, all subsequent actions related to that message would not count toward the numerator.

For measure 3, EPs, eligible hospitals, and CAHs (or their authorized representatives) must incorporate health data obtained from a non-clinical setting in a patient's electronic health record for more than 15 percent of unique patients seen during the EHR reporting period. We note that the use of the term "clinical" means different things in relation to place of service for billing for Medicare and Medicaid services. However, for purposes of this measure only, we are proposing that a non-clinical setting shall be defined as a setting with any provider who is not an EP, eligible hospital or CAH as defined for the Medicare and Medicaid EHR Incentive Programs. Therefore, for this measure, a non-clinical setting is any provider or setting of care which is not an EP, eligible hospital, or CAH in either the Medicare or Medicaid EHR Incentive Programs and where the care provider does not have shared access to the EP, eligible hospital, or CAHs certified EHR. This may include, but is not limited to, health and care-related

data from care providers such as nutritionists, physical therapists, occupational therapists, psychologists, and home health care providers as well as data obtained from patients themselves. We specifically mention this last item and refer to this sub-category as patient-generated health data, which may result from patient self-monitoring of their health (such as recording vital signs, activity and exercise, medication intake, and nutrition), either on their own, or at the direction of a member of the care team. We are proposing this measure in response to requests from providers to support the capture and incorporation of patient-generated health data, and the capture and incorporation of data from a non-clinical setting into an EHR. Providers have expressed a desire to have this information captured in a useful and structured way and made available in the EHR. The capture and incorporation of this information is an integral part of ensuring that providers and patients have adequate information to partner in making clinical care decisions, especially for patients with chronic disease and complex health conditions for whom self-monitoring is an important part of an ongoing care plan.

We are seeking comment on how the information for measure 3 could be captured, standardized, and incorporated into an EHR. For the purposes of this measure, the types of data that would satisfy the measure is broad. It may include, but is not limited to social service data, data generated by a patient or a patient's authorized representatives, advance directives, medical device data, home health monitoring data, and fitness monitor data. In addition, the sources of data vary and may include mobile applications for tracking health and nutrition, home health devices with tracking capabilities such as scales and blood pressure monitors, wearable devices such as activity trackers or heart monitors, patient reported outcome data, and other methods of input for patient and non-clinical setting generated health data. We emphasize that these represent several examples of the data types that could be covered under this measure. We also note that while the scope of data covered by this measure is broad, it may not include data related to billing, payment, or other insurance information. As part of determining the proper scope of this measure, we are seeking comment on the following questions:

- Should the data require verification by an authorized provider?

- Should the incorporation of the data be automated?
- Should there be structured data elements available for this data as fields in an EHR?
- Should the data be incorporated in the CEHRT with or without provider verification?
- Should the provenance of the data be recorded in all cases and for all types of data?

We also seek comment on whether this proposed measure should have a denominator limited to patients with whom the provider has multiple encounters, such as unique patients seen by the provider two or more times during the EHR reporting period. We also seek comment on whether this measure should be divided into two distinct measures. The first measure would include only the specific sub-category of patient-generated health data, or data generated predominantly through patient self-monitoring rather than by a provider. The second measure would include all other data from a non-clinical setting. This would result in the objective including four measures with providers having an option of which two measures to focus on for the EHR reporting period.

We also seek comment on whether the third measure should be proposed for eligible hospitals and CAHs, or remain an option only for eligible professionals. For those commenters who believe it should not be applicable for eligible hospitals and CAHs, we seek further comment on whether eligible hospitals and CAHs should then choose one of the remaining two measures or be required to attest to both.

Providers must attest to the numerator and denominator for all three measures, and must meet the threshold for two of the three measures to meet the objective for Stage 3 of meaningful use:

Proposed Measure 1: We have identified the following for measure 1 of this objective:

Option 1: View, Download, or Transmit to a Third Party

Denominator: Number of unique patients seen by the EP, or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of unique patients (or their authorized representatives) in the denominator who have viewed online, downloaded, or transmitted to a third party the patient's health information.

Threshold: The resulting percentage must be more than 25 percent in order

for an EP, eligible hospital, or CAH to meet this measure.

Option 2: API

Denominator: The number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of unique patients (or their authorized representatives) in the denominator who have accessed their health information through the use of an an ONC-certified API.

Threshold: The resulting percentage must be more than 25 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusions: Applicable for either option discussed previously, the following providers may exclude from the measure:

Any EP who has no office visits during the EHR reporting period may exclude from the measure.

Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measure.

Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measure.

Measure 2: *Denominator:* Number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of patients in the denominator for whom a secure electronic message is sent to the patient, the patient's authorized representatives, or in response to a secure message sent by the patient.

Threshold: The resulting percentage must be more than 35 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP who has no office visits during the EHR reporting period may exclude from the measure.

Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the

latest information available from the FCC on the first day of the EHR reporting period may exclude from the measure.

Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measure.

Measure 3: *Denominator:* Number of unique patients seen by the EP or the number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Numerator: The number of patients in the denominator for whom data from non-clinical settings, which may include patient-generated health data, is captured through the certified EHR technology into the patient record.

Threshold: The resulting percentage must be more than 15 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP who has no office visits during the EHR reporting period may exclude from the measure.

Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measure.

Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measure.

We seek comment on this proposed objective and the related proposed measures.

Objective 7: Health Information Exchange

Improved communication between providers caring for the same patient can help providers make more informed care decisions and coordinate the care they provide. Electronic health records and the electronic exchange of health information, either directly or through health information exchanges, can reduce the burden of such communication. The purpose of this objective is to ensure a summary of care record is transmitted or captured electronically and incorporated into the EHR for patients seeking care among

different providers in the care continuum, and to encourage reconciliation of health information for the patient. This objective promotes interoperable systems and supports the use of CEHRT to share information among care teams.

Proposed Objective: The EP, eligible hospital, or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of certified EHR technology.

In the Stage 2 final rule at 77 FR 53983, we described transitions of care as the movement of a patient from one setting of care (hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home health, rehabilitation facility) to another. Referrals are cases where one provider refers a patient to another provider, but the referring provider also continues to provide care to the patient. In this rule, we also recognize there may be circumstances when a patient refers himself or herself to a setting of care without a provider's prior knowledge or intervention. These referrals may be included as a subset of the existing referral framework and they are an important part of the care coordination loop for which summary of care record exchange is integral. Therefore, a provider should include these instances in their denominator for the measures if the patient subsequently identifies the provider from whom they received care. In addition, the provider may count such a referral in the numerator for each measure if they undertake the action required to meet the measure upon disclosure and identification of the provider from whom the patient received care.

In the Stage 2 final rule, we indicated that a transition or referral within a single setting of care does not qualify as a transition of care (77 FR 53983). We received public comments and questions requesting clearer characterization of when a setting of care can be considered distinct from another setting of care. For example, questions arose whether EPs who work within the same provider practice are considered the same or two distinct settings of care. Similarly, questions arose whether an EP who practices in an outpatient setting that is affiliated with an inpatient facility is considered a separate entity. Therefore, for the purposes of distinguishing settings of care in determining the movement of a patient, we explain that for a transition

or referral, it must take place between providers which have, at the minimum, different billing identities within the EHR Incentive Programs, such as a different National Provider Identifiers (NPI) or hospital CMS Certification Numbers (CCN) to count toward this objective.

Please note that a "referral" as defined here and elsewhere in this proposed rule only applies to the EHR Incentive Programs and is not applicable to other federal regulations.

We stated in the Stage 2 proposed rule at 77 FR 13723 that if the receiving provider has access to the medical record maintained by the provider initiating the transition or referral, then the summary of care record would not need to be provided and that patient may be excluded from the denominators of the measures for the objective. We further note that this access may vary from read-only access of a specific record, to full access with authoring capabilities, depending on provider agreements and system implementation among practice settings. In many cases, a clinical care summary for transfers within organizations sharing access to an EHR may not be necessary, such as a hospital sharing their CEHRT with affiliated providers in ambulatory settings who have full access to the patient information. However, public comments received and questions submitted by the public on the Stage 2 Summary of Care Objective reveal that there may be benefits to the provision of a summary of care document following a transition or referral of a patient, even when access to medical records is already available. For example, a summary of care document would notify the receiving provider of relevant information about the latest patient encounter as well as highlight the most up-to-date information. In addition, the "push" of a summary of care document may function as an alert to the recipient provider of the transition that a patient has received care elsewhere and would encourage the provider to review a patient's medical record for follow-up care or reconciliation of clinical information.

Therefore, we are revising this objective for Stage 3 to allow the inclusion of transitions of care and referrals in which the recipient provider may already have access to the medical record maintained in the referring provider's CEHRT, as long as the providers have different billing identities within the EHR Incentive Program. We note that for a transition or referral to be included in the numerator, if the receiving provider already has access to the CEHRT of the initiating

provider of the transition or referral, simply accessing the patient's health information does not count toward meeting this objective. However, if the initiating provider also sends a summary of care document, this transition can be included in the denominator and the numerator, as long as this transition is counted consistently across the organization.

Proposed Measures: We are proposing that providers must attest to the numerator and denominator for all three measures, but would only be required to successfully meet the threshold for two of the three proposed measures to meet the Health Information Exchange Objective.

Proposed Measure 1: For more than 50 percent of transitions of care and referrals, the EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care: (1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.

Proposed Measure 2: For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, eligible hospital or CAH incorporates into the patient's EHR an electronic summary of care document from a source other than the provider's EHR system.

Proposed Measure 3: For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, eligible hospital, or CAH performs a clinical information reconciliation. The provider must implement clinical information reconciliation for the following three clinical information sets:

- *Medication.* Review of the patient's medication, including the name, dosage, frequency, and route of each medication.
- *Medication allergy.* Review of the patient's known allergic medications.
- *Current Problem list.* Review of the patient's current and active diagnoses.

For the first measure, we are maintaining the requirements established in the Stage 2 final rule to capture structured data within the certified EHR and to generate a summary of care document using CEHRT for purposes of this measure (77 FR 54014). For purposes of this measure, we are requiring that the summary of care document created by CEHRT be sent electronically to the receiving provider.

In the Stage 2 final rule at 77 FR 54016, we specified all summary of care documents must include the following

information in order to meet the objective, if the provider knows it:

- Patient name.
- Referring or transitioning provider's name and office contact information (EP only).
- Procedures.
- Encounter diagnosis.
- Immunizations.
- Laboratory test results.
- Vital signs (height, weight, blood pressure, BMI).
- Smoking status.
- Functional status, including activities of daily living, cognitive and disability status.
- Demographic information (preferred language, sex, race, ethnicity, date of birth).
- Care plan field, including goals and instructions.
- Care team including the primary care provider of record and any additional known care team members beyond the referring or transitioning provider and the receiving provider.
- Discharge instructions (Hospital Only).
- Reason for referral (EP only).

For the 2015 Edition proposed rule, ONC has proposed a set of criteria called the Common Clinical Data Set which include the required elements for the summary of care document, the standards required for structured data capture of each, and further definition of related terminology and use. Therefore, for Stage 3 of meaningful use we are proposing that summary of care documents used to meet the Stage 3 Health Information Exchange objective must include the requirements and specifications included in the Common Clinical Data Set (CCDS) specified by ONC for certification to the 2015 Edition proposed rule published elsewhere in this issue of the **Federal Register**.

We note that ONC's 2015 Edition proposed rule may include additional fields beyond those initially required for Stage 2 of meaningful use as new standards have been developed to accurately capture vital information on patient health. For example, the 2015 Edition proposed rule includes a criterion and standard for capturing the unique device identifier (UDI) for implantable medical devices. The inclusion of the UDI in the CCDS reflects the understanding that UDIs are an important part of patient information that should be exchanged and available to providers who care for patients with implanted medical devices. Hundreds of thousands of Medicare beneficiaries receive some type of implantable medical device each year. Some implants require ongoing monitoring and medication for the device to

perform effectively, such as a mechanical heart valve. Other implanted devices are affected by imaging procedures and are not MRI safe such as some pace makers. Even the variation between specific makes and models of similar devices may impact the clinical processes required to mitigate against patient safety risk. Without readily available data, the patient is put at risk if the provider does not have adequate knowledge of the existence and specific details of medical implants. Therefore, the documentation of UDIs in a patient medical record and the inclusion of that data field within the CCDS requirements for the summary of care documents is a key step toward improving the quality of care and ensuring patient safety. This example highlights the importance of capturing health data in a structured format using specified, transferable standards.

In circumstances where there is no information available to populate one or more of the fields included in the CCDS, either because the EP, eligible hospital, or CAH can be excluded from recording such information (for example, vital signs) or because there is no information to record (for example, laboratory tests), the EP, eligible hospital, or CAH may leave the field blank and still meet the requirements for the measure.

However, all summary of care documents used to meet this objective must be populated with the following information using the CCDS certification standards for those fields:

- Current problem list (Providers may also include historical problems at their discretion).
- A current medication list.
- A current medication allergy list.

We define allergy as an exaggerated immune response or reaction to substances that are generally not harmful. Information on problems, medications, and medication allergies could be obtained from previous records, transfer of information from other providers (directly or indirectly), diagnoses made by the EP or hospital, new medications ordered by the EP or in the hospital, or through querying the patient.

We propose to maintain that all summary of care documents contain the most recent and up-to-date information on all elements. In the event that there are no current diagnoses for a patient, the patient is not currently taking any medications, or the patient has no known medication allergies; the EP, eligible hospital, or CAH must record or document within the required fields that there are no problems, no medications, or no medication allergies recorded for the patient to satisfy the

measure of this objective. The EP or hospital must verify that the fields for problem list, medication list, and medication allergy list are not blank and include the most recent information known by the EP or hospital as of the time of generating the summary of care document.

For summary of care documents at transitions of care, we encourage providers to send a list of items that he or she believes to be pertinent and relevant to the patient's care, rather than a list of all problems, whether active or resolved, that have ever populated the problem list. While a current problem list must always be included, the provider can use his or her judgment in deciding which items historically present on the problem list, medical history list (if it exists in CEHRT), or surgical history list are relevant given the clinical circumstances.

Similarly, for Stage 3 we have received comments from stakeholders and through public forums and correspondence on the potential of allowing only clinically relevant laboratory test results and clinical notes (rather than all laboratory tests results and clinical notes) in the summary of care document for purposes of meeting the objective. We believe that while there may be a benefit and efficiency to be gained in the potential to limit laboratory test results or clinical notes to those most relevant for a patient's care; a single definition of clinical relevance may not be appropriate for all providers, all settings, or all individual patient diagnosis. Furthermore, we note that should a reasonable limitation around a concept of "clinical relevance" be added; a provider must still have the CEHRT functionality to include and send all labs or clinical notes. Therefore, we defer to provider discretion on the circumstances and cases wherein a limitation around clinical relevance may be beneficial and note that such a limitation would be incumbent on the provider to define and develop in partnership with their health IT developer as best fits their organizational needs and patient population. We specify that while the provider has the discretion to define the relevant clinical notes or relevant laboratory results to send as part of the summary of care record, providers must be able to provide all clinical notes or laboratory results through an electronic transmission of a summary of care document if that level of detail is subsequently requested by a provider receiving a transition of care or referral or the patient is transitioning to another setting of care. We note that this proposal would apply for lab results,

clinical notes, problem lists, and the care plan within the summary of care document.

For the second measure, we are proposing to address the other end of the transition of care continuum. In the Stage 2 rule, we limited the action required by providers to sending an electronic transmission of a summary of care document. We did not have a related requirement for the recipient of that transmission. We did not adopt a certification requirement for the receiving end of a transition or referral or for the measure related to sending the summary, as that is a factor outside the sending provider's immediate control. However, in Stage 3 of meaningful use, we are proposing a measure for the provider as the recipient of a transition or referral requiring them to actively seek to incorporate an electronic summary of care document into the patient record when a patient is referred to them or otherwise transferred into their care. This proposal is designed to complete the electronic transmission loop and support providers in using CEHRT to support the multiple roles a provider plays in meaningful health information exchange.

For the purposes of defining the cases in the denominator, we are proposing that what constitutes "unavailable" and therefore, may be excluded from the denominator, will be that a provider—

- Requested an electronic summary of care record to be sent and did not receive an electronic summary of care document; and
- Queried at least one external source via HIE functionality and did not locate a summary of care for the patient, or the provider does not have access to HIE functionality to support such a query.

We seek comment on whether electronic alerts received by EPs from hospitals when a patient is admitted, seen in the emergency room or discharged from the hospital—so called "utilization alerts"—should be included in measure two, or as a separate measure. Use of this form of health information exchange is increasingly rapidly, driven by hospital and EP efforts to improve care transitions and reduce readmissions. We also seek comment on which information from a utilization alert would typically be incorporated into a patient's record and how this is done today.

For both the first and second measures, we are proposing that a provider may use a wide range of health IT system for health information exchange to receive or send an electronic summary of care document, but must use their certified EHR technology to create the summary of

care document sent or to incorporate the summary of care document received into the patient record. We are also proposing that the receipt of the summary of care document (CCDA) may be passive (provider is sent the CCDA and incorporates it) or active (provider requests a direct transfer of the CCDA or provider queries an HIE for the CCDA). In the Stage 2 proposed rule, we noted the benefits of requiring standards for the transport mechanism for health information exchange consistently nationwide (77 FR 13723). We requested public comment in that proposed rule on the Nationwide Health Information Network specifications and a governance mechanism for health information exchange to be established by ONC. In the final rule, a governance mechanism option was included in the second measure for the Stage 2 summary of care objective at 77 FR 54020. In this Stage 3 proposed rule, we again seek comment on a health information exchange governance mechanism. Specifically we seek comment on whether providers who create a summary of care record using CEHRT for purposes of Measure 1 should be permitted to send the created summary of care record either—(1) through any electronic means; or (2) in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network. We additionally seek comment on whether providers who are receiving a summary of care record using CEHRT for the purposes of Measure 2 should have a similar requirement for the transport of summary of care documents requested from a transitioning provider. Finally, we seek comment on how a governance mechanism established by ONC at a later date could be incorporated into the EHR Incentive Programs for purposes of encouraging interoperable exchange that benefits patients and providers, including how the governance mechanism should be captured in the numerator, denominator, and thresholds for both the first (send) and second (receive) measures of this Health Information exchange objective.

For the third measure, we are proposing a measure of clinical information reconciliation which incorporates the Stage 2 objective for medication reconciliation and expands the options to allow for the reconciliation of other clinical information such as medication allergies, and problems which will allow providers additional flexibility in meeting the measure in a way that is relevant to their scope of practice. In the

Stage 2 final rule, we outlined the benefits of medication reconciliation, which enables providers to validate that the patient's list of active medications is accurate (77 FR 54011 through 54012). This activity improves patient safety, improves care quality, and improves the validity of information that the provider shares with others through health information exchange. We believe that reconciliation of medication allergies and problems affords similar benefits.

For this proposed measure, we specify that the EP, eligible hospital, or CAH that receives the patient into their care should conduct the clinical information reconciliation. It is for the receiving provider that up-to-date information will be most crucial to make informed clinical judgments for patient care. We reiterate that this measure does not dictate what subset of information must be included in reconciliation. Information included in the process is determined by the provider's clinical judgment of what is most relevant to patient care.

For this measure, we propose to define clinical information reconciliation as the process of creating the most accurate patient-specific information in one or more of the specified categories by using the clinical information reconciliation capability of their certified EHR technology which will compare the "local" information to external/incoming information that is being incorporated into the certified EHR technology from any external source. We refer providers to the standards and certification criteria for clinical information reconciliation proposed in ONC's 2015 Edition proposed rule published elsewhere in this issue of the **Federal Register**.

As with medication reconciliation, we believe that an electronic exchange of information following the transition of care of a patient is the most efficient method of performing clinical information reconciliation.

We recognize that workflows to reconcile clinical information vary widely across providers and settings of care, and we request comment on the challenges that this objective might present for providers, and how such challenges might be mitigated, while preserving the policy intent of the measure. In particular, we solicit comment on the following:

- Automation and Manual Reconciliation. The Stage 2 measure does not specify whether reconciliation must be automated or manual. Some providers have expressed concern over the automatic inclusion of data in the patient record from referring providers, while others have indicated that

requiring manual reconciliation imposes significant workflow burden. We also seek comment on whether the use and display of meta-tagged data could address concerns related to the origin of data and thereby permit more automated reconciliation of these data elements.

- Review of Reconciled Information. Depending on clinical setting, this measure could be accomplished through manual reconciliation or through automated functionality. In either scenario, should the reconciliation or review of automated functionality be performed only by the same staff allowed under the Stage 3 requirements for the Computerized Provider Order Entry objective?

- What impact would the requirement of clinical information reconciliation have on workflow for specialists? Are there particular specialties where this measure would be difficult to meet?

- What additional exclusions, if any, should be considered for this measure?

We also encourage comment on the proposal to require reconciliation of all three clinical information reconciliation data sets, or if we should potentially require providers to choose 2 of 3 information reconciliation data sets relevant to their specialty or patient population. We expect that most providers would find that conducting clinical information reconciliation for medications, medication allergies, and problem lists is relevant for every patient encountered. We solicit examples describing challenges and burdens that providers who deliver specialist care or employ unique clinical workflow practices may experience in completing clinical information reconciliation for all three data sets and whether an exclusion should be considered for providers for whom such reconciliation may not be relevant to their scope of practice or patient population. Additionally, we solicit comments around the necessity to conduct different types of clinical information reconciliation of data for each individual patient. For example, it is possible that the data for certain patients should always be reviewed for medication allergy reconciliation, when it may not be as relevant to other patient populations.

We propose that to meet this objective, a provider must attest to the numerator and denominator for all three measures but would only be required to successfully meet the threshold for two of the three proposed measures. We invite public comment on this proposal.

Measure 1: To calculate the percentage of the first measure, CMS

and ONC have worked together to define the following for this measure:

Denominator: Number of transitions of care and referrals during the EHR reporting period for which the EP or eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) was the transferring or referring provider.

Numerator: The number of transitions of care and referrals in the denominator where a summary of care record was created using certified EHR technology and exchanged electronically.

Threshold: The percentage must be more than 50 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: An EP neither transfers a patient to another setting nor refers a patient to another provider during the EHR reporting period.

* Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the measures.

Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Measure 2: To calculate the percentage of the second measure, CMS and ONC have worked together to define the following for this measure:

Denominator: Number of patient encounters during the EHR reporting period for which an EP, eligible hospital, or CAH was the receiving party of a transition or referral or has never before encountered the patient and for which an electronic summary of care record is available.

Numerator: Number of patient encounters in the denominator where an electronic summary of care record received is incorporated by the provider into the certified EHR technology.

Threshold: The percentage must be more than 40 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP, eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period is excluded from this measure.

Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the measures.

Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Measure 3: To calculate the percentage, CMS and ONC have worked together to define the following for this measure:

Denominator: Number of transitions of care or referrals during the EHR reporting period for which the EP or eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) was the recipient of the transition or referral or has never before encountered the patient.

Numerator: The number of transitions of care or referrals in the denominator where the following three clinical information reconciliations were performed: medication list, medication allergy list, and current problem list.

Threshold: The resulting percentage must be more than 80 percent in order for an EP, eligible hospital, or CAH to meet this measure.

Exclusion: Any EP, eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period is excluded from this measure.

Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude the measure.

Any eligible hospital or CAH will be excluded from the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

We welcome comment on these proposals.

Objective 8: Public Health and Clinical Data Registry Reporting

This objective builds on the requirements set forth in the Stage 2 final rule (77 FR 54021 through 54026). In addition, this objective includes improvements to the Stage 2 measures, supports innovation that has occurred since the Stage 2 rule was released, and adds flexibility in the options that an eligible provider has to successfully report.

Further, this objective places increased focus on the importance of the ongoing lines of communication that should exist between providers and public health agencies (PHAs) or as further discussed later in this section, between providers and clinical data registries (CDRs). Providers' use of certified EHR technology can increase the flow of secure health information and reduce the burden that otherwise could attach to these important communications. The purpose of this Stage 3 objective is to further advance communication between providers and PHAs or CDRs, as well as strengthen the capture and transmission of such health information within the care continuum.

In this Stage 3 proposed rule, we are proposing changes to the Stage 1 and Stage 2 public health and specialty registry objectives to consolidate the prior objectives and measures into a single objective in alignment with efforts to streamline the program and support flexibility for providers. We propose to include a new measure for case reporting to reflect the diverse ways that providers can electronically exchange data with PHAs and CDRs. In addition, we are using new terms such as public health registries and clinical data registries to incorporate the Stage 2 designations for cancer registries and specialized registries under these categories which are used in the health care industry to designate a broader range of registry types. We further explain the use of these terms within the specifications outlined for each applicable measure.

Proposed Objective: The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

For Stage 3, we are proposing to remove the prior "ongoing submission" requirement and replace it with an "active engagement" requirement. Depending on the measure, the ongoing

submission requirement from the Stage 1 and Stage 2 final rules required the successful ongoing submission of applicable data from certified EHR technology to a PHA or CDR for the entire EHR reporting period. As part of the Stage 2 final rule, we provided examples demonstrating how ongoing submission could satisfy the measure (77 FR 54021). However, stakeholders noted that the ongoing submission requirement does not accurately capture the nature of communication between providers and a PHA or CDR, and does not consider the many steps necessary to arrange for registry submission to a PHA or CDR. Given this feedback, we believe that "active engagement" as defined later in this section is more aligned with the process providers undertake to report to a CDR or to a PHA.

For purposes of meeting this new objective, EPs, eligible hospitals and CAHs would be required to demonstrate that "active engagement" with a PHA or CDR has occurred. Active engagement means that the provider is in the process of moving towards sending "production data" to a PHA or CDR, or— is sending production data to a PHA or CDR. We note that the term "production data" refers to data generated through clinical processes involving patient care, and it is here used to distinguish between this data and "test data" which may be submitted for the purposes of enrolling in and testing electronic data transfers. We propose that "active engagement" may be demonstrated by any of the following options:

Active Engagement Option 1—Completed Registration to Submit Data: The EP, eligible hospital, or CAH registered to submit data with the PHA or, where applicable, the CDR to which the information is being submitted; registration was completed within 60 days after the start of the EHR reporting period; and the EP, eligible hospital, or CAH is awaiting an invitation from the PHA or CDR to begin testing and validation. This option allows providers to meet the measure when the PHA or the CDR has limited resources to initiate the testing and validation process. Providers that have registered in previous years do not need to submit an additional registration to meet this requirement for each EHR reporting period.

Active Engagement Option 2—Testing and Validation: The EP, eligible hospital, or CAH is in the process of

testing and validation of the electronic submission of data. Providers must respond to requests from the PHA or, where applicable, the CDR within 30 days; failure to respond twice within an EHR reporting period would result in that provider not meeting the measure.

Active Engagement Option 3—Production: The EP, eligible hospital, or CAH has completed testing and validation of the electronic submission and is electronically submitting production data to the PHA or CDR.

We also propose to provide support to providers seeking to meet the requirements of this objective by creating a centralized repository of national, state, and local PHA and CDR readiness. In the Stage 2 final rule (77 FR 54021), we noted the benefits of developing a centralized repository where a PHA could post readiness updates regarding their ability to accept electronic data using specifications prescribed by ONC for the public health objectives. We also published, pursuant to the Paperwork Reduction Act of 1995, a notice in the **Federal Register** on February 7, 2014 soliciting public comment on the proposed information collection required to develop the centralized repository on public health readiness (79 FR 7461). We considered the comments and we now propose moving forward with the development of the centralized repository. The centralized repository is integral to meaningful use and is expected to be available by the start of CY 2017. We expect that the centralized repository will include readiness updates for PHAs and CDRs at the state, local, and national level. We welcome your comments on the use and structure of the centralized repository.

Proposed Measures: We are proposing a total of six possible measures for this objective. EPs would be required to choose from measures 1 through 5, and would be required to successfully attest to any combination of three measures. Eligible hospitals and CAHs would be required to choose from measures one through six, and would be required to successfully attest to any combination of four measures. The measures are as shown in Table 5. As noted, measures four and five for Public Health Registry Reporting and Clinical Data Registry Reporting may be counted more than once if more than one Public Health Registry or Clinical Data Registry is available.

TABLE 5—MEASURES FOR OBJECTIVE 8: PUBLIC HEALTH AND CLINICAL DATA REGISTRY REPORTING OBJECTIVE

Measure	Maximum times measure can count towards objective for EP	Maximum times measure can count towards objective for eligible hospital or CAH
Measure 1—Immunization Registry Reporting	1	1
Measure 2—Syndromic Surveillance Reporting	1	1
Measure 3—Case Reporting	1	1
Measure 4—Public Health Registry Reporting*	3	4
Measure 5—Clinical Data Registry Reporting**	3	4
Measure 6—Electronic Reportable Laboratory Results	N/A	1

* EPs, eligible hospitals, and CAHs may choose to report to more than one public health registry to meet the number of measures required to meet the objective.

** EPs, eligible hospitals, and CAHs may choose to report to more than one clinical data registry to meet the number of measures required to meet the objective.

For EPs, we propose that an exclusion for a measure does not count toward the total of three measures. Instead, in order to meet this objective, an EP would need to meet three of the total number of measures available to them. If the EP qualifies for multiple exclusions and the remaining number of measures available to the EP is less than three, the EP can meet the objective by meeting all of the remaining measures available to them and claiming the applicable exclusions. Available measures include ones for which the EP does not qualify for an exclusion.

For eligible hospitals and CAHs, we propose that an exclusion for a measure does not count toward the total of four measures. Instead, in order to meet this objective an eligible hospital or CAH would need to meet four of the total number of measures available to them. If the eligible hospital or CAH qualifies for multiple exclusions and the total number of remaining measures available to the eligible hospital or CAH is less than four, the eligible hospital or CAH can meet the objective by meeting all of the remaining measures available to them and claiming the applicable exclusions. Available measures include ones for which the eligible hospital or CAH does not qualify for an exclusion.

We note that we are proposing to allow EPs, eligible hospitals, and CAHs to choose to report to more than one public health registry to meet the number of measures required to meet the objective. We are also proposing to allow EPs, eligible hospitals, and CAHs to choose to report to more than one clinical data registry to meet the number of measures required to meet the objective. We believe that this flexibility allows for EPs, eligible hospitals, and CAHs to choose reporting options that align with their practice and that will aid the provider’s ability to care for their patients.

Measure 1—Immunization Registry Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

We believe the immunization registry reporting measure remains a priority for Stage 3 because the exchange of information between certified EHR technology and immunization registries allows a provider to use the most complete immunization history available to inform decisions about the vaccines a patient may need. Public health agencies and providers also use immunization information for emergency preparedness and to estimate population immunization coverage levels of certain vaccines.

We propose that to successfully meet the requirements of this measure, bidirectional data exchange between the provider’s certified EHR technology and the immunization registry/IIS is required. We understand that many states and local public health jurisdictions are exchanging immunization data bidirectionally with providers, and that the number of states and localities able to support bidirectional exchange continues to increase. In the 2015 Edition proposed rule published by ONC elsewhere in this issue of the **Federal Register**, the ONC is proposing to adopt a bidirectional exchange standard for reporting to immunization registries/IIS. We believe this functionality is important for patient safety and improved care because it allows the provider to use the most complete immunization record possible to make decisions on whether a patient needs a vaccine. Immunization registries and health IT systems also are able to

provide immunization forecasting functions which can inform discussions between providers and patients on what vaccines they may need in the future and the timeline for the receipt of such immunizations. Therefore, we believe that patients, providers, and the public health community would benefit from technology that can accommodate bidirectional immunization data exchange. We welcome comment on this proposal.

Exclusion for Measure 1: Any EP, eligible hospital, or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure if the EP, eligible hospital, or CAH: (1) Does not administer any immunizations to any of the populations for which data is collected by their jurisdiction’s immunization registry or immunization information system during the EHR reporting period; (2) operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data at the start of the EHR reporting period.

Measure 2—Syndromic Surveillance Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care ambulatory setting for EPs, or an emergency or urgent care department for eligible hospitals and CAHs (POS 23). This measure remains a policy priority for Stage 3 because electronic syndromic surveillance is valuable for early detection of outbreaks, as well as monitoring disease and condition trends. We are

distinguishing between EPs and eligible hospital or CAHs reporting locations because, as discussed in the Stage 2 final rule, few PHAs appeared to have the ability to accept non-emergency or non-urgent care ambulatory syndromic surveillance data electronically (77 FR 53979). We continue to observe differences in the infrastructure and current environments for supporting electronic syndromic surveillance data submission to PHAs between eligible hospitals or CAHs and EPs. Because eligible hospitals and CAHs send syndromic surveillance data using different methods as compared to EPs, we are defining slightly different exclusions for each setting as described later in this section.

Exclusion for EPs for Measure 2: Any EP meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the EP: (1) Does not treat or diagnose or directly treat any disease or condition associated with a syndromic surveillance system in their jurisdiction; (2) operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from EPs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from EPs at the start of the EHR reporting period.

Exclusion for eligible hospitals/CAHs for Measure 2: Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the eligible hospital or CAH: (1) Does not have an emergency or urgent care department; (2) operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data from eligible hospitals or CAHs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs at the start of the EHR reporting period.

Measure 3—Case Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.

This is a new reporting option that was not part of Stage 2. The collection of electronic case reporting data greatly improves reporting efficiencies between providers and the PHA. Public health agencies collect “reportable

conditions”, as defined by the state, territorial, and local PHAs to monitor disease trends and support the management of outbreaks. In many circumstances, there has been low reporting compliance because providers do not know when, where, or how to report. In some cases, the time burden to report can also contribute to low reporting compliance. However, electronic case reporting presents a core benefit to public health improvement and a variety of stakeholders have identified electronic case reporting as a high value element of patient and continuity of care. Further, we believe that electronic case reporting reduces burdensome paper-based and labor-intensive case reporting. Electronic reporting will support more rapid exchange of case reporting information between PHAs and providers and can include structured questions or data fields to prompt the provider to supply additional required or care-relevant information.

To support case reporting, the ONC has proposed a certification criterion that includes capabilities to enable certified EHR systems to send initial case reporting data and receive a request from the public health agency for supplemental or ad hoc structured data in the 2015 Edition proposed rule, published elsewhere in this issue of the **Federal Register**.

Exclusion for Measure 3: Any EP, eligible hospital, or CAH meeting one or more of the following criteria may be excluded from the case reporting measure if the EP, eligible hospital, or CAH: (1) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction’s reportable disease system during the EHR reporting period; (2) operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data at the start of the EHR reporting period.

Measure 4—Public Health Registry Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit data to public health registries.

In the Stage 2 final rule, we were purposefully general in our use of the term “specialized registry” (other than a cancer registry) to encompass both registry reporting to public health agencies and clinical data registries in order to prevent inadvertent exclusion of certain registries through an attempt

to be more specific (77 FR 54030). In response to insight gained from the industry through listening sessions, public forums, and responses to the February 2014 Public Health Reporting RFI; we propose to carry forward the concept behind this broad category from Stage 2, but also propose to split public health registry reporting from clinical data registry reporting into two separate measures which better define the potential types of registries available for reporting. We propose to define a “public health registry” as a registry that is administered by, or on behalf of, a local, state, territorial, or national PHA and which collects data for public health purposes. While immunization registries are a type of public health registry, we propose to keep immunization registry reporting separate from the public health registry reporting measure to retain continuity from Stage 1 and 2 policy in which immunization registry reporting was a distinct and separate objective (77 FR 54023). We believe it is important to retain the public health registry reporting option for Stage 3 because these registries allow the public health community to monitor health and disease trends, and inform the development of programs and policy for population and community health improvement.

We reiterate that any EP, eligible hospital, or CAH may report to more than one public health registry to meet the total number of required measures for the objective. For example, if a provider meets this measure through reporting to both the National Hospital Care Survey and the National Healthcare Safety Network registry, the provider could get credit for meeting two measures. ONC will consider the adoption of standards and implementation guides in future rulemaking. Should these subsequently be finalized, they may then be adopted as part of the certified EHR technology definition as it relates to meeting the public health registry reporting measure through future rulemaking for the EHR Incentive Programs.

We further note that ONC adopted standards for ambulatory cancer case reporting in its final rule “2014 Edition, Release 2 EHR Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange” (79 FR 54468) and we provided EPs the option to select the cancer case reporting menu objective in the Stage 2 final rule (77 FR 54029 through 54030). We included cancer registry reporting as a separate objective from specialized registry reporting

because it was more mature in its development than other registry types, not because other reporting was intended to be excluded from meaningful use. For the Stage 3 public health registry reporting measure, given the desire to provide more flexible options for providers to report to the registries most applicable for their scope of practice, we propose that EPs would have the option of counting cancer case reporting under the public health registry reporting measure. We note that cancer case reporting is not an option for eligible hospitals and CAHs under this measure because hospitals have traditionally diagnosed or treated cancers and have the infrastructure needed to report cancer cases.

Exclusions for Measure 4: Any EP, eligible hospital, or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure if the EP, eligible hospital, or CAH: (1) Does not diagnose or directly treat any disease or condition associated with a public health registry in their jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

Measure 5—Clinical Data Registry Reporting: The EP, eligible hospital, or CAH is in active engagement to submit data to a clinical data registry.

As discussed in the Public Health Registry Reporting measure, we propose to split specialized registry reporting into two separate, clearly defined measures: Public health registry reporting and clinical data registry reporting. In Stage 2 for EPs, reporting to specialized registries is a menu objective and this menu objective includes reporting to clinical data registries. For Stage 3, we propose to include clinical data registry reporting as an independent measure. The National Quality Registry Network defines clinical data registries as those that record information about the health status of patients and the health care they receive over varying periods of time.¹² We propose to further differentiate between clinical data registries and public health registries as

follows: For the purposes of meaningful use, “public health registries” are those administered by, or on behalf of, a local, state, territorial, or national public health agencies; and “clinical data registries” are administered by, or on behalf of, other non-public health agency entities. We believe that clinical data registries are important for providing information that can inform patients and their providers on the best course of treatment and for care improvements, and can support specialty reporting by developing reporting for areas not usually covered by PHAs but that are important to a specialist’s provision of care. Clinical data registries can also be used to monitor health care quality and resource use.

As noted previously, we reiterate that any EP, eligible hospital, or CAH may report to more than one clinical data registry to meet the total number of required measures for this objective. ONC will consider the adoption of standards and implementation guides in future rulemaking. Should these subsequently be finalized, they may then be adopted as part of the certified EHR technology definition as it relates to meeting the clinical data registry reporting measure through future rulemaking for the EHR Incentive Programs.

Exclusions for Measure 5: Any EP, eligible hospital, or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure if the EP, eligible hospital, or CAH: (1) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no clinical data registry for which the EP, eligible hospital, or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

Measure 6—Electronic Reportable Laboratory Result Reporting: The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results. This measure is available to eligible hospitals and CAHs only. Electronic reportable laboratory result reporting to PHAs is required for eligible hospitals and CAHs in Stage 2 (77 FR 54021). We propose to retain this measure for Stage 3 to promote the

exchange of laboratory results between eligible hospitals/CAHs and PHAs for improved timeliness, reduction of manual data entry errors, and more complete information.

Exclusion for Measure 6: Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result reporting measure if the eligible hospital or CAH: (1) Does not perform or order laboratory tests that are reportable in their jurisdiction during the EHR reporting period; (2) operates in a jurisdiction for which no public health agency is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results from an eligible hospital or CAH at the start of the EHR reporting period.

The Use of CEHRT for the Public Health and Clinical Data Registry Reporting Objective

As proposed previously, the Public Health and Clinical Data Registry Reporting objective requires active engagement with a public health agency to submit electronic public health data from certified EHR technology. ONC defined the standards and certification criteria to meet the definition of CEHRT in its 2011, 2014, and 2014 Release 2 Edition EHR certification criteria rules (see section II.B. of the “2014 Edition, Release 2 EHR Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange” for a full description of ONC’s regulatory history; (79 FR 54434)). For example, ONC adopted standards for immunization reporting (see § 170.314(f)(1) and (f)(2)), inpatient syndromic surveillance (see § 170.314(f)(3) and (f)(7)), ELR (see § 170.314(f)(4)), and cancer case reporting (see § 170.314(f)(5) and (f)(6)) in its 2014 Edition final rule.

We support ONC’s intent to promote standardized and interoperable exchange of public health data across the country. Therefore, to meet all of the measures within this public health objective EPs, eligible hospitals, and CAHs must use CEHRT as we propose to define it under § 495.4 in this proposed rule and use the standards included in the 2015 Edition proposed rule published elsewhere in this edition of the **Federal Register**. We anticipate that as new public health registries and clinical data registries are created, ONC and CMS will work with the public health community and clinical specialty societies to develop ONC-certified

¹² <https://download.ama-assn.org/resources/doc/cqi/x-pub/nqm-what-is-clinical-data-registry.pdf>.

electronic reporting standards for those registries so that providers have the option to count participation in those registries under the measures of this objective. ONC will look to adopt such standards, as appropriate, in future rules published by ONC.

We welcome public comment on these proposals.

II. Provisions of the Proposed Regulations

A. Meaningful Use Requirements, Objectives and Measures

2. Certified EHR Technology (CEHRT) Requirements

Certified EHR technology is defined for the Medicare and Medicaid EHR Incentive Programs at 42 CFR 495.4, which references ONC's definition of CEHRT under 45 CFR 170.102. The definition establishes the requirements for EHR technology that must be used by providers to meet the meaningful use objectives and measures. The Stage 2 final rule requires that CEHRT must be used by EPs, eligible hospitals, and CAHs to satisfy their CQM reporting requirements under the Medicare and Medicaid EHR Incentive Programs. In addition, the CQM data reported to CMS must originate from EHR technology that is certified to "capture and export" in accordance with 45 CFR 170.314(c)(1) and "electronic submission" in accordance with 45 CFR 170.314(c)(3) (77 FR 54053).

On September 4, 2014, CMS and ONC published a final rule in the **Federal Register** (79 FR 52910 through 52933) that, among other things, modified the meaningful use requirements for 2014 and the CEHRT definition.

First, we granted flexibility to providers who experienced product availability issues that affected their ability to fully implement EHR technology certified to the 2014 Edition of certification criteria (79 FR 52913 through 52926). We allowed those EPs, eligible hospitals, and CAHs to continue using either EHR technology certified to the 2011 Edition, or a combination of EHR technology certified to the 2011 Edition and 2014 Edition, for the EHR reporting periods in CY 2014 and FY 2014. EPs, eligible hospitals, and CAHs could take one of these approaches if they were unable to fully implement EHR technology certified to the 2014 Edition for an EHR reporting period in 2014 due to delays in the availability of EHR technology certified to the 2014 Edition.

Second, we established that in order to receive an incentive payment for 2014 under Medicaid for adopting, implementing, or upgrading CEHRT, a

provider must adopt, implement, or upgrade to EHR technology certified to the 2014 Edition and meet the CEHRT definition (79 FR 52925 through 52926).

Finally, ONC revised the CEHRT definition under 45 CFR 170.102 to align with our policy allowing for the use of EHR technology certified to the 2011 Edition, or a combination of EHR technology certified to the 2011 Edition and 2014 Edition, in 2014 (79 FR 52930).

For further detail on the changes to the requirements for 2014 and CEHRT definition, we refer readers to the 2014 CEHRT Flexibility final rule (79 FR 52910 through 52933).

a. CEHRT Definition for the EHR Incentive Programs

As we have stated previously in rulemaking, the statute and regulations require EPs, eligible hospitals, and CAHs to use "Certified EHR Technology" if they are to be considered meaningful EHR users and eligible for incentive payments under Medicare or Medicaid, and to avoid payment adjustments under Medicare (for example, see section 1848(o)(2)(A)(i) of the Act, and 42 CFR 495.4). However, in contrast to prior rulemaking cycles where ONC has established a meaningful-use-specific CEHRT definition for the EHR Incentive Programs that CMS has adopted by cross-reference under 42 CFR 495.4, we propose to take a different approach under which we would define the term "Certified EHR Technology," and that definition would be specific to the EHR Incentive Programs.

This proposed change is designed to simplify the overall regulatory relationship between ONC and CMS rules for stakeholders and to ensure that relevant CMS policy for the EHR Incentive Programs is clearly referenced in CMS regulations. For example, ONC's definition of CEHRT under 45 CFR 170.102 includes the compliance dates for EPs, eligible hospitals, and CAHs to use EHR technology certified to a particular edition of certification criteria to meet the CEHRT definition and for purposes of the EHR Incentive Programs, such as the requirement to use EHR technology certified to the 2014 Edition beginning in 2015. Under the proposed new approach, we would establish through rulemaking for the EHR Incentive Programs (either with stand-alone rulemaking or through other vehicles such as the annual Medicare payment rules) the compliance dates by which providers must use EHR technology certified to a particular edition of certification criteria to meet the CEHRT definition, which would be

reflected in our regulations under 42 CFR part 495 rather than ONC's regulations under 45 CFR part 170.

b. Defining CEHRT for 2015 Through 2017 and for 2018 and Subsequent Years

In adopting a CEHRT definition specific for the EHR Incentive Programs, we propose to include, as currently for the ONC CEHRT definition under 45 CFR 170.102, the relevant Base EHR definitions adopted by ONC in 45 CFR 170.102 and other ONC certification criteria relevant to the EHR Incentive Programs. We refer readers to ONC's 2015 Edition proposed rule published elsewhere in this issue of the **Federal Register** for the proposed 2015 Edition Base EHR definition and discussion of the 2014 Edition Base EHR definition. We are including the Base EHR definition(s) because as ONC explained in the 2014 Edition final rule "2014 Edition, Release 2 EHR Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange" (77 FR 54443 through 54444) the "Base EHR" essentially serves as a substitute for the term "Qualified EHR" in the definition of CEHRT. The term "Qualified EHR" is defined in section 3000(13) of the PHSA, to include certain capabilities listed in that section, and is included in the statutory definition of "certified EHR technology" for the EHR Incentive Programs (for example, see section 1848(o)(4) of the Act). The Base EHR definition(s) also include additional capabilities as proposed by ONC that we agree all providers should have that are participating in the EHR Incentive Programs to support their attempts to meet meaningful use objectives and measures as well as interoperable health information exchange.

We propose to define the editions of certification criteria that may be used for years 2015 through 2017 to meet the CEHRT definition. At a minimum, EPs, eligible hospitals, and CAHs would be required to use EHR technology certified to the 2014 Edition certification criteria for their respective EHR reporting periods in 2015 through 2017. A provider may also upgrade to the 2015 Edition prior to 2018 to meet the required certified EHR technology definition for the EHR reporting periods in 2015, 2016, or 2017, or they may use a combination of 2014 and 2015 Editions prior to 2018 if they have modules from both Editions which meet the requirements for the objectives and measures or if they fully upgrade during an EHR reporting period.

Based on experience with delays in the availability of EHR technology certified to the 2014 Edition for providers to implement and use to meet meaningful use for an EHR reporting period in 2014, we propose to include as part of the CEHRT definition a longer period of time for providers to use technology certified to the 2014 Edition in an effort to give providers more time in updating their technology to the 2015 Edition before the EHR reporting period in 2018. We also propose to make the use of a combination of technology certified to the 2014 Edition and 2015 Edition to meet the CEHRT definition more flexible in 2015 through 2017 by taking into account ONC's proposed new privacy and security certification approach for health IT (see ONC's 2015 Edition proposed rule published elsewhere in this issue of the **Federal Register**). Specifically, as a provider updates to technology certified to the 2015 Edition, the provider would not necessarily need to continue to meet the privacy and security capability requirements of the 2014 Edition Base EHR definition because the technology they adopt certified to the 2015 Edition would include necessary privacy and security capabilities. Additionally, because ONC is proposing, for the 2015 Edition, to no longer require certification of Health IT Modules to capabilities that support meaningful use objectives with percentage-based measures, we propose to include these capabilities (45 CFR 170.314(g)(1) or (2) or 45 CFR 170.315(g)(1) or (2)), as applicable, in the CEHRT definition for 2015 through 2017 so that providers have technology that can appropriately record and calculate meaningful use measures. We note that there are many combinations of 2014 and 2015 Edition certified technologies that could be used to successfully meet the transitions of care requirements included in the 2014 and 2015 Edition Base EHR definitions for the purposes of meeting meaningful use objectives and measures. We believe we have identified all combinations in the proposed regulation text under § 495.4 that could be used to meet the CEHRT definition through 2017 and be used for the purposes of meeting meaningful use objectives and measures. We welcome comments on the accuracy of the identified available options.

We propose that starting with 2018, all EPs, eligible hospitals, and CAHs would be required to use technology certified to the 2015 Edition to meet the CEHRT definition and demonstrate meaningful use for an EHR reporting period in 2018 and subsequent years.

The CEHRT definition would include, for the reasons discussed previously, meeting the 2015 Edition Base EHR definition and having other important capabilities, that include the capabilities to—

- Record or create and incorporate family health history;
- Capture patient health information such as advance directives;
- Record numerators and denominators for meaningful use objectives with percentage-based measures and calculate the percentages;
- Calculate and report clinical quality measures; and
- Any other capabilities needed to be a Meaningful EHR User.

For information on 2015 Edition certification criteria that include these capabilities and are associated with proposed Meaningful Use objectives for Stage 3, please see the 2015 Edition proposed rule published elsewhere in this issue of the **Federal Register**. We expect that the certification criteria with capabilities that support CQM calculation and reporting would be jointly proposed with CQM reporting requirements in a separate rulemaking.

c. Proposed Definition for CEHRT

For the reasons stated previously, we propose to adopt a definition of Certified EHR Technology under 42 CFR 495.4 for the Medicare and Medicaid EHR Incentive Programs that would apply for the EHR reporting periods in 2015 up to and including 2017 and for the EHR reporting periods in 2018 and subsequent years. We refer readers to ONC's 2015 Edition proposed rule published elsewhere in this issue of the **Federal Register** for further explanation of the concepts and terms used in our proposed definition of Certified EHR Technology, including the 2014 Edition Base EHR definition, 2015 Edition Base EHR definition, certification criteria, and the regulation text under 45 CFR part 170.

B. Reporting on Clinical Quality Measures Using Certified EHR Technology by EPs, Eligible Hospitals, and Critical Access Hospitals

1. Clinical Quality Measure (CQM) Requirements for Meaningful Use in 2017 and Subsequent Years

Under sections 1848(o)(2)(A), 1886(n)(3)(A), and 1814(l)(3)(A) of the Act and 42 CFR 495.4, EPs, eligible hospitals, and CAHs must report on CQMs selected by CMS using certified EHR technology, as part of being a meaningful EHR user under the Medicare and Medicaid EHR Incentive Programs.

In regard to the selection of CQMs, we expect to continue to include CQMs that align with the National Quality Strategy; as well as, the our Quality Strategy. We also expect to consider programmatic goals and outcome measures that would advance patient and population health.

a. Clinical Quality Measure Reporting Requirements for EPs

Section 1848(o)(2)(B)(iii) of the Act requires that in selecting measures for EPs for the Medicare EHR Incentive Program, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting, including reporting under subsection (k)(2)(C) for the Physician Quality Reporting System (PQRS). Consistent with that requirement, in the Stage 2 final rule, we finalized a policy to align certain aspects of reporting CQMs for the Medicare EHR Incentive Program for EPs with reporting under the PQRS. Specifically, we stated that Medicare EPs who participate in both the PQRS and the Medicare EHR Incentive Program will satisfy the CQM reporting component of meaningful use if they submit and satisfactorily report PQRS CQMs under the PQRS's EHR reporting option using CEHRT (77 FR 54058).

Section 1848(m)(7) of the Act requires the Secretary to develop a plan to integrate reporting on quality measures under the PQRS with reporting requirements under the Medicare EHR Incentive Program relating to the meaningful use of electronic health records. Therefore, it is our goal to align the reporting requirements for the CQM component of meaningful use under the Medicare EHR Incentive Program and for PQRS wherever possible.

Historically, most requirements for the Medicare and Medicaid EHR Incentive Programs have been established through stand-alone rulemaking, such as the rules for Stage 1 (75 FR 44314 through 44588) and Stage 2 (77 FR 53968 through 54162), which span multiple program years. This limited our ability to align the EHR Incentive Program with the requirements established in the annual Medicare payment rules for other CMS quality programs affecting physicians and other EPs.

To further our goals of alignment and avoiding redundant or duplicative reporting across the various CMS quality reporting programs, we intend to address CQM reporting requirements for the Medicare and Medicaid EHR Incentive Program for EPs for 2017 and subsequent years in the Medicare Physician Fee Schedule (PFS) rulemaking, which also establishes the requirements for PQRS and other

quality programs affecting EPs. We note that the form and manner of reporting of CQMs for Medicare EPs would also be included in the PFS, while for Medicaid we would continue to allow the states to determine form and method requirements subject to CMS approval. We propose to continue the policy of establishing certain CQM requirements that apply for both the Medicare and Medicaid EHR Incentive Programs including a common set of CQMs and the reporting periods for CQMs in the EHR Incentive Programs. However, we believe that receiving and reviewing public comments for various CMS quality programs at one time (for example, EHR Incentive Program, PQRS, Physician Compare); and finalizing the requirements for these programs simultaneously, would allow us to better align these programs for EPs to support streamlined reporting and program efficacy. We propose to continue to support active communication with providers to facilitate the sharing of information related to CQM selection and reporting, the announcement of opportunities for public comment on CQM selection and reporting, and upcoming or relevant CQM program milestones in partnership with state Medicaid programs and the Medicare quality reporting programs. We propose to continue to post the defined CQM sets and the published electronic specifications for CQM that are in use for all aligned programs on the CMS Web site as currently posted on the eCQM Library page: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html.

b. CQM Reporting Requirements for Eligible Hospitals and Critical Access Hospitals

Section 1886(n)(3)(B)(iii) of the Act requires that, in selecting measures for eligible hospitals for the Medicare EHR Incentive Program, and establishing the form and manner for reporting measures, the Secretary shall seek to avoid redundant or duplicative reporting with reporting otherwise required, including reporting under section 1886(b)(3)(B)(viii) of the Act, the Hospital IQR Program.

Similar to our intentions for EPs discussed previously, and to further our alignment goal among CMS quality reporting programs for eligible hospitals and CAHs, and avoid redundant or duplicative reporting among hospital programs, we intend to address CQM reporting requirements for the Medicare and Medicaid EHR Incentive Program for eligible hospitals and CAHs for 2016,

2017, and future years, in the Inpatient Prospective Payment System (IPPS) rulemaking. IPPS rulemaking also establishes the requirements for the Hospital IQR Program and other quality programs affecting hospitals. We intend to include all Medicare EHR Incentive Program requirements related to CQM reporting in the IPPS rulemaking including, but not limited to, new program requirements, reporting requirements, reporting and submission periods, reporting methods, and information regarding the CQMs. As with EPs, for the Medicaid EHR Incentive Program we would continue to allow the states to determine form and method requirements subject to CMS approval. However, as previously noted, this proposal would continue the policy of establishing certain CQM requirements that apply for both the Medicare and Medicaid EHR Incentive Programs including a common set of CQMs and the reporting periods for CQMs in the EHR Incentive Programs. We believe that receiving and reviewing public comments for various CMS quality programs at one time and finalizing the requirements for these programs simultaneously would allow us to better align these programs for eligible hospitals and CAHs, allow more flexibility into the Medicare and Medicaid EHR Incentive Programs, and add overall value and consistency by providing us the opportunity to address public comments that affect multiple programs at one time. We propose to continue to support active communication with providers to facilitate the sharing of information related to CQM selection and reporting, the announcement of opportunities for public comment on CQM selection and reporting, and upcoming or relevant CQM program milestones in partnership with state Medicaid programs and the Medicare quality reporting programs. We propose to continue to post the defined CQM sets and the published electronic specifications for CQM that are in use for all aligned programs on the CMS Web site as currently posted on the eCQM Library page: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html.

2. CQM Reporting Period

In the Stage 2 final rule, we finalized a reporting period for CQMs for EPs, eligible hospitals, and CAHs (see 77 FR 54049 through 54051). In the FY 2015 IPPS final rule, we began to shift CQM reporting to a calendar year basis for eligible hospitals and CAHs for the Medicare EHR Incentive Program (79 FR

50319 through 50321). We established that for eligible hospitals and CAHs that submit CQMs electronically in 2015, the reporting period is one calendar quarter from Q1, Q2, or Q3 of CY 2015 (79 FR 50321).

As discussed in sections II.A.1.c.(1).(b).(i) and II.F. of this proposed rule, we are proposing to require an EHR reporting period of 1 full calendar year for meaningful use for providers participating in the Medicare EHR Incentive Program, with a limited exception for Medicaid providers demonstrating meaningful use for the first time. We are proposing to require the same length for the CQM reporting period for EPs, eligible hospitals, and CAHs beginning in 2017. As noted, we are proposing a limited exception for Medicaid providers demonstrating meaningful use for the first time who would have a CQM reporting period of any continuous 90 days that is the same 90-day period as their EHR Reporting Period.

We believe full year reporting would allow for the collection of more comparable data across CMS quality programs and increase alignment across those programs. The more robust data set provided by a full year reporting period offers more opportunity for alignment than the data set provided by a shorter reporting period, especially compared across years. We further believe this full calendar year reporting period for CQMs would reduce the complexity of reporting requirements for the Medicare EHR Incentive Program by streamlining the reporting timeline for providers for CQMs and meaningful use objectives and measures. We welcome comment on the following proposals.

a. CQM Reporting Period for EPs

With the previously stated considerations in mind, and in an effort to align with other CMS quality reporting programs such as the PQRS, we propose to require for CQM reporting under the EHR Incentive Program a reporting period of one full calendar year for all EPs participating in the Medicare and Medicaid EHR Incentive Program, with a limited exception for Medicaid providers demonstrating meaningful use for the first time who would have a CQM reporting period of any continuous 90 days that is the same 90-day period as their EHR Reporting Period. These reporting periods would apply beginning in CY 2017 for all EPs participating in the EHR Incentive Program.

b. CQM Reporting Period for Eligible Hospital/CAH

For eligible hospitals and CAHs in 2017 and subsequent years, we are proposing to require a reporting period of 1 full calendar year which consists of 4 quarterly data reporting periods for providers participating in the Medicare and Medicaid EHR Incentive Program, with a limited exception for Medicaid providers demonstrating meaningful use for the first time who would have a CQM reporting period of any continuous 90 days that is the same 90-day period as their EHR Reporting Period. More details of the form and manner will be provided in the IPPS rulemaking cycle.

c. Reporting Flexibility EPs, Eligible Hospitals, CAHs 2017

In order to align with the flexibility option of participation in Meaningful Use in 2017 (see section I.I.C.1.b. of this proposed rule), we are proposing that EPs, eligible hospitals, and CAHs would be able to have more flexibility to report CQMs in one of two ways in 2017—via electronic reporting or attestation. First EPs, eligible hospitals, and CAHs may choose to report eCQMs electronically using the CQMs finalized for use in 2017 using the most recent version of the eCQMs (electronic specifications), which would be the electronic specifications of the CQMs published by CMS in 2016. Alternately, a provider may choose to continue to attest also using the most recent (2016 version) eCQM electronic specifications. We note that the intent to allow attestation in 2017 is to provide flexibility for providers transitioning between versions of CEHRT in 2017 and believe that requiring the most recent version of the annual updates should not be a significant burden given that developers do not need to recertify a product each time CQM specifications are updated.

However, we seek comment on if CMS should consider allowing providers to report using another earlier version of the specifications.

We note that, unlike the flexible options established in rulemaking in 2014 (79 FR 52927 through 52930), providers may select the CQMs they choose to report separately from the Stage objectives and measures of meaningful use for their EHR reporting period in 2017.

We invite public comment on our proposals.

3. Reporting Methods for CQMs

In the Stage 2 final rule, we finalized the reporting methods for CQMs for EPs (77 FR 54075 through 54078), eligible hospitals, and CAHs (77 FR 54087 through 54089) for the Medicare EHR Incentive Program, which included reporting electronically, where feasible, or by attestation. To further align the Medicare and Medicaid EHR Incentive Programs with programs such as PQRS and the Hospital IQR program, starting in 2017, we propose to continue to encourage electronic submission of CQM data for all EPs, eligible hospitals, and CAHs where feasible; however, as outlined in section I.I.C.1.b. of this proposed rule, we would allow attestation for CQMs in 2017. For 2018 and subsequent years, we are proposing that providers participating in the Medicare program must electronically report where feasible and that attestation to CQMs would no longer be an option except in certain circumstances where electronic reporting is not feasible. This would include providers facing circumstances which render them unable to electronically report (such as a data submission system failure, natural disaster, or certification issue outside the control of the provider) who may attest to CQMs if they also attest that

electronically reporting was not feasible for their demonstration of meaningful use for a given year. We believe that the collection and electronic reporting of data through health information technology would greatly simplify and streamline reporting for many CMS quality reporting programs and reduce the burden of quality measure reporting for providers who participate in these programs. We also believe this would further encourage the adoption and use of certified EHR technology by allowing EPs, eligible hospitals, and CAHs to report data for multiple programs through a single electronic submission. Through electronic reporting, EPs, eligible hospitals, and CAHs would be able to leverage EHRs to capture, calculate, and electronically submit quality data to CMS for the Medicare EHR Incentive Program. We note that we intend to address the form and manner of electronic reporting in future Medicare payment rules.

For the Medicaid EHR Incentive Program, as in the Stage 2 rulemaking (77 FR 54089), we propose that states would continue in Stage 3 to be responsible for determining whether and how electronic reporting of CQMs would occur, or whether they wish to continue to allow reporting through attestation. If a state does require such electronic reporting, the state is responsible for sharing the details of the process with its provider community. We anticipate that whatever means states have deployed for capturing CQMs electronically for Stages 1 and 2 would be similar for reporting in Stage 3. However, we note that subject to our prior approval, this is within the states' purview. We propose for Stage 3 that the states would establish the method and requirements, subject to our prior approval, for the electronic capture and reporting of CQMs from CEHRT.

PROPOSED eCQM REPORTING TIMELINES FOR MEDICARE & MEDICAID EHR INCENTIVE PROGRAM

Year	2017 only	2017 only	2018 and subsequent years.	2018 and subsequent years.
Reporting Method Available.	Attestation	Electronic Reporting	Attestation	Electronic Reporting.
Provider Type who May Use Method.	All Medicare providers	All Medicare Providers	Medicare Providers with circumstances rendering them unable to eReport.	All Medicare Providers.
CQM Reporting Period	Medicaid providers must refer to state requirements for reporting. 1 CY for Medicare	Medicaid providers must refer to state requirements for reporting. 1 CY for Medicare	Medicaid providers must refer to state requirements for reporting. 1 CY for Medicare	Medicaid providers must refer to state requirements for reporting. 1 CY for Medicare.
	1 CY for returning Medicaid. 90 days for first time meaningful user Medicaid.	1 CY for returning Medicaid. 90 days for first time meaningful user Medicaid.	1 CY for returning Medicaid. 90 days for first time meaningful user Medicaid.	1 CY for returning Medicaid. 90 days for first time meaningful user Medicaid.

PROPOSED eCQM REPORTING TIMELINES FOR MEDICARE & MEDICAID EHR INCENTIVE PROGRAM—Continued

eCQM Version Required (CQM electronic specifications update).	2016 Annual Update	2016 Annual Update	2016 Annual Update or more recent version.	2017 Annual Update.
CEHRT Edition Required ..	2014 Edition Or 2015 Edition	2014 Edition Or 2015 Edition	2015 Edition	2015 Edition.

We invite public comments on our proposals.

a. Quality Reporting Data Architecture Category III (QRDA–III) Option for Eligible Hospitals and CAHs

In the Stage 2 final rule (77 FR 54088), we finalized two options for eligible hospitals and CAHs to electronically submit CQMs beginning in FY 2014 under the Medicare EHR Incentive Program. Option 1 was to submit aggregate level CQM data using QRDA–III electronically. Option 2 was to submit data electronically using a method similar to the 2012 and 2013 Medicare EHR Incentive Program electronic reporting pilot for eligible hospitals and CAHs, which used QRDA–I (patient-level data).

We noted in the FY 2014 and 2015 IPPS/LTCH PPS final rules (78 FR 50904 through 50905 and 79 FR 50321 through 50322) that we had determined that the electronic submission of aggregate-level data using QRDA–III would not be feasible in 2014 or 2015 for eligible hospitals and CAHs under the Medicare EHR Incentive Program. We stated that we would reassess this policy for future reporting periods.

In this proposed rule, we are proposing to remove the QRDA–III option for eligible hospitals and CAHs, as we have found this is not an option for electronic reporting as we move forward with the EHR Incentive Program, we believe the calculations, per the QRDA–III, are not advantageous to quality improvement. As the EHR Incentive Program further aligns with the Hospital IQR program, we intend to continue utilizing the electronic reporting standard of QRDA–I patient level data that we finalized in the FY 2015 IPPS rule (79 FR 50322), which will allow the same level of CQM reporting, and use and analysis of these data for quality improvement initiatives.

As we understand the need to support state flexibility, we are also proposing that states would continue to have the option, subject to our prior approval, to allow or require QRDA–III for CQM reporting.

4. CQM Specification and Changes to the Annual Update

In the Stage 2 final rule, we stated that we do not intend to use notice and comment rulemaking as a means to update or modify electronic CQM (eCQM) specifications (77 FR 54055). In general, it is the role of the measure steward to make changes to a CQM in terms of the initial patient population, numerator, denominator, potential exclusions, logic, and value sets. We recognize that it may be necessary to update CQM specifications after they have been published to ensure their continued clinical relevance, accuracy, and validity. CQM specification updates may include administrative changes, such as adding the NQF endorsement number to a CQM, correcting faulty logic, adding or deleting codes as well as providing additional implementation guidance for a CQM.

These changes are described through the annual updates to the electronic specifications for EHR submission published by CMS. CQMs are currently tracked on a version basis as updates are made and we require EPs, eligible hospitals, and CAHs to submit the versions of the CQMs as identified on our Web site. The Web site contains all versions of the CQMs since reporting via attestation does not require the most recent version of the CQMs, but electronic reporting of the CQMs does require the most recent version to be reported. Because we require the most recent version of the CQM specifications to be used for electronic reporting methods, we understand that EHR vendors must make CQM updates on an annual basis. We also understand that providers must regularly implement those updates to stay current with the most recent CQM version.

We continue to evaluate the CQM update timeline and look for ways to provide CQM updates timely, so that vendors can develop, test, and deploy these updates and providers can implement those updates as necessary. We have the flexibility to update CQMs so they remain clinically relevant, accurate, and valid. While we are not proposing any change to our policy on updating CQM specifications in this proposed rule, we seek comment on our annual update timeline and suggestions

for how to improve the CQM update process.

5. EHR Technology Certification Requirements for Reporting of CQMs

In the 2014 Edition EHR Certification Criteria Final Rule, ONC finalized certain certification criteria to support the MU objectives and CQMs set forth by CMS. In that rule, ONC also specified that in order for an EP, eligible hospital, or CAH to have EHR technology that meets the Base EHR definition, the EHR technology must be certified to a minimum of nine CQMs for EPs or 16 CQMs for eligible hospitals and CAHs (77 FR 54264 through 54265; see also 45 CFR 170.102). This is the same number required for quality reporting to the Medicare and Medicaid EHR Incentive Programs, the PQRS EHR reporting and, beginning in 2015, the electronic reporting option under the Hospital IQR Program. In certain cases, an EP, eligible hospital or CAH may purchase an EHR product that is certified to the minimum number of CQMs and discover that, for at least one of those CQMs, they do not have data on which to report. In these cases, the EP (77 FR 54058 through 54059), eligible hospital or CAH (77 FR 54051) would report a zero denominator for one or more CQMs.

We believe EHRs should be certified to more than the minimum number of CQMs required by one or more CMS quality reporting programs so that EPs, eligible hospitals, and CAHs have a choice of which CQMs to report, and could therefore choose to report on CQMs most applicable to their patient population or scope of practice.

We realize that requiring EHRs to be certified to more than the minimum number of CQMs required by the Medicare and Medicaid EHR Incentive Programs may increase the burden on EHR vendors. However, in the interest of EPs, eligible hospitals, and CAHs being able to choose to report eCQMs that represent their patient populations, we would like to see EP vendors certify to all eCQMs that are in the EP selection list, or eligible hospital/CAH vendors certify to all eCQMs in the selection list for those stakeholders.

We are also considering a phased approach such that the number of CQMs required for the vendors to have

certified would increase each year until EHR products are required to certify all CQMs required for reporting by EPs, eligible hospitals, and CAHs. For example, in year one of this phased plan, we might require that EHRs be certified to at least 18 of 64 available CQMs for EPs and 22 of 29 available CQMs for eligible hospitals and CAHs; in year two, we might require at least 36 CQMs for EPs and all 29 CQMs for eligible hospitals and CAHs; in subsequent years of the plan, we would increase the number of required CQMs for EPs until the EHR is certified to all applicable CQMs for EPs, eligible hospitals, and CAHs.

We have also considered alternate plans that would require EHRs to be certified to more than the minimum number of CQMs required for reporting, but would not require the EHR to be certified to all available CQMs. For example, we might require that EHRs be certified to a certain core set of CQMs plus an additional 9 CQMs for EPs, and a certain core set of CQMs plus an additional 16 CQMs for eligible hospitals and CAHs, which the EHR vendor could choose from the list of available CQMs.

We note that the specifics of this plan would be outlined in separate notice-and-comment rulemaking such as the PFS or IPPS rules. We specifically seek comment on this issue of a plan to increase the number of CQMs to which an EHR is certified.

6. Electronic Reporting of CQMs

As previously stated in the Medicare and Medicaid EHR Incentive Programs Stage 2 final rule (77 FR 54051 through 54053), CQM data submitted by EPs, eligible hospitals, and CAHs are required to be captured, calculated and reported using certified EHR technology. We received numerous questions from stakeholders expressing confusion over what it means to capture data in certified EHR technology. Specifically, stakeholders question whether they may manually abstract data into the EHR from a patient's chart. We do not consider the manual abstraction of data from the EHR to be capturing the data using certified EHR technology. We believe that electronic information interfaced or electronically transmitted from non-certified EHR technology, such as lab information systems, automated blood pressure cuffs, and electronic scales, into the certified EHR, would satisfy the "capture" requirement, as long as that data is visible to providers in the EHR.

C. Demonstration of Meaningful Use and Other Issues

1. Demonstration of Meaningful Use

a. Common Methods of Demonstration in Medicare and Medicaid

We are proposing to continue our common method for demonstrating meaningful use in both the Medicare and Medicaid EHR Incentive Programs. The demonstration methods we adopt for Medicare would automatically be available to the States for use in their Medicaid programs.

b. Methods for Demonstration of the Stage 3 Criteria of Meaningful Use for 2017 and Subsequent Years

We are proposing to continue the use of attestation as the method for demonstrating that an EP, eligible hospital, or CAH has met the Stage 3 objectives and measures of meaningful use. We are proposing to continue the existing optional batch file process for attestation in lieu of individual Medicare EP attestation through our registration and attestation system. This batch reporting process ensures that meaningful use of certified EHR technology continues to be measured at the individual level, while promoting efficiencies for group practices that must submit attestations on large groups of individuals (77 FR 54089).

We would continue to leave open the possibility for CMS and the states to test options for demonstrating meaningful use that utilize existing and emerging HIT products and infrastructure capabilities. These options could involve the use of registries or the direct electronic reporting of measures associated with the objectives of meaningful use. We would not require any EP, eligible hospital, or CAH to participate in this testing in order to receive an incentive payment or avoid the payment adjustment.

For 2017 only, we are proposing changes to the attestation process for the meaningful use objectives and measures, which would allow flexibility for providers during this transitional year. These proposals are supported by a similar flexibility proposed in the requirements for the Edition of CEHRT a provider may use in 2017 as further discussed in section II.A.I.C.(1).(b).(3) of this proposed rule. In addition, we discuss the attestation changes proposed for CQM reporting in detail under section II.B.2.a. of this proposed rule.

(1) Meaningful Use Objective and Measures in 2017

In order to allow all providers to successfully transition to Stage 3 of meaningful use for a full year-long EHR

reporting period in 2018, we are proposing to allow flexibility for the EHR Incentive Programs in 2017. This transition period would allow providers to establish and test their processes and workflows for Stage 3 of meaningful use prior to 2018. Specifically, for 2017, we are proposing that providers may either repeat a year at their current stage or move up stage levels. However, for 2017, a provider may not move backward in their progression. Under this proposal, providers who participated in Stage 1 in 2016 may choose to attest to the Stage 1 objective and measures, or they may move on to Stage 2 or Stage 3 objectives and measures for an EHR reporting period in 2017. Providers who participated in Stage 2 in 2016 may choose to attest to the Stage 2 objectives and measures or move on to Stage 3 objectives and measures for an EHR reporting period in 2017. However, under no circumstances, may providers return to Stage 1. In 2018, all providers, regardless of their prior participation or the stage level chosen in 2017, would be required to attest to Stage 3 objectives and measures for an EHR reporting period in 2018.

(2) CEHRT and Stage Flexibility in 2017

Based on the delays providers experienced with fully implementing the EHR technology certified to the 2014 Edition (as further described in the 2014 CEHRT Flexibility final rule (79 FR 52910 through 52933) we believe it is necessary to preemptively prepare for the upgrade to EHR technology certified to the 2015 Edition and the transition to Stage 3. Preparation for the upgrade would ensure that providers and developers have adequate time to certify, install, fully implement the software, and establish the processes and workflows for the objectives and measures for providers moving to the next stage of the EHR Incentive Programs. Accordingly, we propose allowing providers flexible CEHRT options for 2017. These options may impact the selection of objectives and measures to which a provider can attest. Specifically, under the CEHRT options for 2017, we propose that providers would have the option to continue to use EHR technology certified to the 2014 Edition, in whole or in part, for an EHR reporting period in 2017. We note that providers who use only the EHR technology certified to the 2014 Edition for an EHR reporting period in 2017 may not choose to attest to the Stage 3 objectives and measures as those objectives and measures require the support of EHR technology certified to the 2015 Edition.

Providers using only EHR technology certified in whole or in relevant part to the 2014 Edition certification criteria may attest to the objectives and measures of meaningful use in the following manner:

- If a provider first demonstrated meaningful use in 2015 or 2016, they may attest to Stage 1 objectives and measures or Stage 2 objectives and measures.

- If a provider first demonstrated meaningful use in any year prior to 2015, they may attest to the Stage 2 objectives and measures.

Providers using EHR technology certified in whole or in relevant part to the 2015 Edition certification criteria may elect to attest to the objectives and measures of meaningful use in the following manner:

- If a provider first demonstrated meaningful use in 2015 or 2016, they may attest to Stage 1 objectives and measures, Stage 2 objectives and measures, or Stage 3 objectives and measures if they have all the 2015 Edition functionality required to meet all Stage 3 objectives.

- If a provider first demonstrated meaningful use in any year prior to 2015, they may attest to Stage 2 objectives and measures, or Stage 3 objectives and measures if they have all the 2015 Edition functionality required to meet all Stage 3 objectives.

We note that all providers would be required to fully upgrade to EHR technology certified to the 2015 Edition for the EHR reporting period in 2018. We also reiterate that providers may elect to attest to Stage 3 of the program using EHR technology certified to the 2015 Edition beginning in 2017. We further stress that the use of 2011 CEHRT, although an option under the 2014 CEHRT Flexibility final rule (79 FR 52913 through 52914), is not an option under this proposal. However, as part of this proposal, we would like to seek comment on alternate flexibility options. Specifically, we are seeking comment on whether the flexible option to attest to Stages 1 or 2 should be limited to only those providers who could not fully implement EHR technology certified to the 2015 Edition in 2017. We are also seeking comment on whether those providers with fully implemented EHR technology certified to the 2015 Edition in 2017 should be required to attest to Stage 3 only in 2017. Finally, we seek comment on whether providers should not have the option to attest to Stage 3 in 2017 regardless of an upgrade to EHR technology certified to the 2015 Edition in 2017, and should instead be required to wait to demonstrate Stage 3 until

2018 using EHR technology certified to the 2015 Edition.

We welcome comments on these proposals.

(3) CQM Flexibility in 2017

In the 2014 CEHRT Flexibility final rule, we did not allow providers to separate their CQM reporting selection from the year of meaningful use objectives they reported on. We did not allow this reporting for a number of reasons including how we defined CQMs, as well as the number of CQMs reporting changes occurring between Stage 1 in 2011 through 2013, and Stage 1 and 2 in 2014. For further discussion, we direct readers to 79 FR 52927 through 52930.

To report CQMs for 2017, we propose to allow greater flexibility by proposing to split the use of CEHRT for CQM reporting from the use of CEHRT for the objectives and measures. This means that providers would be able to separately report CQMs using EHR technology certified to the 2015 Edition even if they use EHR technology certified to the 2014 Edition for the meaningful use objectives and measures for an EHR reporting period in 2017. Providers may also use EHR technology certified to the 2015 Edition for their meaningful use objectives and measures in 2017 and use EHR technology certified to the 2014 Edition for their CQM reporting for an EHR reporting period in 2017.

For an EHR reporting period in 2017, EPs, eligible hospitals, and CAHs may choose to report eCQMs electronically using the CQMs finalized for use in 2017 using the most recent version of the eCQMs (electronic specifications), which would be the electronic specifications of the CQMs published by CMS in 2016. Alternately, a provider may choose to continue to attest to the CQMs established for use in 2017 also using the most recent (2016 version) eCQM electronic specifications. These options are available for provider using either EHR technology certified to the 2014 Edition or EHR technology certified to the 2015 Edition. These flexible options for an EHR reporting period in 2017 are further discussed in sections II.B.2.a. of this proposed rule. An EP, eligible hospital, or CAH must use certified EHR technology, successfully attest to the meaningful use objectives and measures, and successfully submit CQMs to be a meaningful EHR user. We note that states may determine the form and method of CQM submission for participants in the Medicaid program subject to our approval as outline in sections II.B.3 and II.F.3. of this

proposed rule. However, the selection of CQMs and the minimum reporting period are the same for providers in both Medicare and Medicaid as outlined in section II.B.3. of this proposed rule.

Similar to our rationale under the 2014 CEHRT Flexibility final rule (79 FR 52910 through 52933), we believe the proposals outlined for attestation in 2017 would allow providers the flexibility to choose the option which applies to their particular circumstances and use of CEHRT. Upon attestation, providers may select one of the proposed options available for their participation year and EHR Edition. The EHR Incentive Program Registration and Attestation System would then prompt the provider to attest to meeting the objectives, measures, and CQMs applicable under that option. We further propose that auditors would be provided guidance related to reviewing attestations associated with the options for using CEHRT in 2017, as was done for 2014.

We welcome comment on this proposal.

c. EHR Reporting Period in 2017 and Subsequent Years

We are proposing, with limited exceptions outlined in section II.F.1. of this proposed rule, that the EHR reporting period in 2017 would be a full calendar year for all providers. We encourage providers to begin Stage 3 in 2017. However, under the current timeline shown in Table 3, we recognize that providers first demonstrating meaningful use under Stage 1 in 2016 or 2017 or under Stage 2 in 2016 or 2017 must begin Stage 3 in 2018. We further recognize providers scheduled to begin Stage 3 in 2017 that instead choose to meet the Stage 2 criteria in 2017 must begin Stage 3 in 2018. However, in 2018, all providers, except as outlined in section II.F.1. of this proposed rule, must report based on a full calendar year EHR reporting period for the Stage 3 objectives and measures. In addition, in 2018, all providers must use EHR technology certified to the 2015 Edition for the full EHR reporting period in order to successfully demonstrate meaningful use.

For CQM reporting in 2018 and subsequent years, as outlined in section II.B.3 of this proposed rule, we are proposing that providers participating in the Medicare program must electronically report, where feasible, and that attestation to CQMs would no longer be an option except in circumstances where electronic reporting is not feasible. This would include providers facing circumstances which render them unable to

electronically report (such as a data submission system failure, natural disaster, or certification issue outside the control of the provider) who may attest to CQMs if they also attest that electronically reporting was not feasible for their demonstration of meaningful use for a given year.

We welcome public comment on this proposal.

2. Data Collection for Online Posting, Program Coordination, and Accurate Payments

We propose to continue posting Stage 1 and Stage 2 aggregate and individual performance and participation data resulting from the EHR Incentive programs online regularly for public use. We further note our intent to potentially publish the performance and participation data on Stage 3 objectives and measures of meaningful use in alignment with quality programs which utilize publicly available performance data such as physician compare.

In addition to the data already being collected under our regulations, as outlined in section III. of this proposed rule, we propose to collect the following information from providers to ensure providers keep their information up-to-date through the system of record for their National Provider Identifier (NPI) in the National Plan & Provider Enumeration System:

- Primary Practice Address (address, city, state zip, country code, etc.).
- Primary Business/Billing Address (address, city, state, zip, country code, etc.).
- Primary License information (for example, provide medical license in at least one state (or territory)).
- Contact Information (phone number, fax number, and contact email address).
- Health Information Exchange Information:

++ Such as DIRECT address required (if available).

++ If DIRECT address is not available, Electronic Service Information is required.

++ If DIRECT address is available, Electronic Service Information is optional in addition to DIRECT address.

We do not propose any changes to the registration for the Medicare and Medicaid EHR Incentive Programs.

3. Interaction With Other Programs

There are no proposed changes to the ability of providers to participate in the Medicare and Medicaid EHR Incentive Programs and other CMS programs. We continue to work on aligning the data collection and reporting of the various CMS programs, especially in the area of

clinical quality measurement. See sections II.B.1. through II.B.6. of this proposed rule for the proposed alignment initiatives for CQMs.

D. Payment Adjustments and Hardship Exceptions

Sections 4101(b) and 4102(b) of the HITECH Act, amending sections 1848, 1853, and 1886 of the Act, require reductions in payments to EPs, eligible hospitals, and CAHs that are not meaningful users of certified EHR technology, beginning in CY 2015 for EPs, FY 2015 for eligible hospitals, and in cost reporting periods beginning in FY 2015 for CAHs.

1. Statutory Basis for Payment Adjustment and Hardship Exceptions for EPs

Section 1848(a)(7) of the Act provides for payment adjustments, effective for CY 2015 and subsequent years, for EPs as defined in 42 CFR 495.100, who are not meaningful EHR users during the relevant EHR reporting period for the year. Section 1848(a)(7) provides that in general, beginning in 2015, if an EP is not a meaningful EHR user for the EHR reporting period for the year, then the Medicare physician fee schedule (PFS) amount for covered professional services furnished by the EP during the year (including the fee schedule amount for purposes of determining a payment based on the fee schedule amount) is adjusted to equal the “applicable percent” of the fee schedule amount that would otherwise apply. The term “applicable percent” is defined in section 1848(a)(7)(A)(ii) of the Act as: (I) for 2015, 99 percent (or, in the case of an EP who was subject to the application of the payment adjustment [if the EP was not a successful electronic prescriber] under section 1848(a)(5) of the Act for 2014, 98 percent); (II) for 2016, 98 percent; and (III) for 2017 and each subsequent year, 97 percent.

In addition, section 1848(a)(7)(A)(iii) of the Act provides that if, for CY 2018 and subsequent years, the Secretary finds the proportion of EPs who are meaningful EHR users is less than 75 percent, the applicable percent shall be decreased by 1 percentage point for EPs who are not meaningful EHR users from the applicable percent in the preceding year, but that in no case shall the applicable percent be less than 95 percent.

Section 1848(a)(7)(B) of the Act provides that the Secretary may, on a case-by-case basis, exempt an EP who is not a meaningful EHR user for the reporting period for the year from the application of the payment adjustment if the Secretary determines that

compliance with the requirements for being a meaningful EHR user would result in a significant hardship, such as in the case of an EP who practices in a rural area without sufficient internet access. The exception is subject to annual renewal, but in no case may an EP be granted an exception for more than 5 years.

We established regulations implementing these statutory provisions under 42 CFR 495.102. We refer readers to the final rules for Stages 1 and 2 (75 FR 44442 through 44448 and 77 FR 54093 through 54102) for more information.

2. EHR Reporting Period for Determining Whether an EP Is Subject to the Payment Adjustment for CY 2018 and Subsequent Calendar Years

Section 1848(a)(7)(E)(ii) of the Act provides the Secretary with broad authority to choose the EHR reporting period that will apply for purposes of determining the payment adjustments for CY 2015 and subsequent years. In the Stage 2 final rule (77 FR 54095 through 54097), we adopted a policy that the EHR reporting periods for the payment adjustments will begin and end prior to the year of the payment adjustment. We stated that this is based on our desire to avoid creating a situation in which it might be necessary either to recoup overpayments or make additional payments after a determination is made about whether the payment adjustment should apply, and the resulting implications for beneficiary coinsurance.

Specifically, we finalized under § 495.4 of the regulations that for EPs, the EHR reporting period for a payment adjustment year is the full calendar year that is 2 years before the payment adjustment year. For example, the full calendar year of 2015 would be the EHR reporting period for the CY 2017 payment adjustment year. We also finalized an exception to this rule for EPs who have never successfully attested to meaningful use. Stated generally, under this exception, for an EP who is demonstrating meaningful use for the first time, the EHR reporting period for a payment adjustment year is any continuous 90-day period. For a full description of this exception, including limitations on when the continuous 90-day period must occur in relation to the payment adjustment year and the deadlines for registration and attestation, we refer readers to the definition of “EHR reporting period for a payment adjustment year” under § 495.4 of the regulations and the discussion in the Stage 2 final rule (77 FR 54095 through 54096). We

established that these policies apply for the CY 2015 payment adjustment year and subsequent payment adjustment years.

However, in this Stage 3 proposed rule, we propose to eliminate the exception discussed previously for a 90-day EHR reporting period for new meaningful EHR users beginning with the EHR reporting period in 2017, with a limited exception for Medicaid EPs demonstrating meaningful use for the first time. We propose that for EPs who have successfully demonstrated meaningful use in a prior year as well as those who have not, the EHR reporting period for a payment adjustment year would be the full calendar year that is 2 years before the payment adjustment year. For example, for all EPs demonstrating meaningful use, the full CY 2017 would be the EHR reporting period for the CY 2019 payment adjustment year. To avoid a payment adjustment in CY 2019, EPs must demonstrate meaningful use of certified EHR technology for an EHR reporting period of the entire CY 2017. This policy would continue to apply in subsequent years.

As discussed in sections II.A.1.a. and II.F.1. of this proposed rule, we are proposing to maintain a 90-day EHR reporting period for the first payment year based on meaningful use for Medicaid EPs demonstrating meaningful use for the first time. We recognize that these EPs may be subject to payment adjustments under Medicare if they fail to demonstrate meaningful use, and thus we propose that the same 90-day EHR reporting period used for the Medicaid incentive payment would also apply for purposes of the Medicare payment adjustment for the payment adjustment year two years after the calendar year in which the provider demonstrates meaningful use. We note under our current policy, if an EP has never successfully demonstrated meaningful use, the EHR reporting period for a payment adjustment year is any continuous 90-day period that both begins in the calendar year 1 year before the payment adjustment year and ends at least 3 months before the end of such prior year. We do not propose to maintain this policy, and thus for Medicaid EPs who are new meaningful EHR users, the 90-day EHR reporting period for a payment adjustment year must occur within the calendar year that is 2 years before the payment adjustment year. These proposals for Medicaid EPs would apply beginning with the EHR reporting period in CY 2017.

We provide the following example:

Example A: If an EP has never successfully demonstrated meaningful use prior to CY 2017 and demonstrates under the Medicaid EHR Incentive Program that he or she is a meaningful EHR user for the first time in CY 2017, the EHR reporting period for the Medicaid incentive payment would be any continuous 90-day period within CY 2017. The same 90-day period would also serve as the EHR reporting period for the CY 2019 payment adjustment year under Medicare. This 90-day period would not serve as the EHR reporting period for the CY 2018 payment adjustment year under Medicare even if the EP registers for and attests to meaningful use by October 1, 2017. The EP would have to demonstrate meaningful use for an EHR reporting period of the full CY 2018 to earn an incentive payment under Medicaid for the CY 2018 payment year and avoid the payment adjustment under Medicare for the CY 2020 payment adjustment year.

We propose these changes to further our goal to align reporting requirements under the EHR Incentive Program and the reporting requirements for various CMS quality reporting programs, to respond to stakeholders who cited difficulty with following varying reporting requirements, and to simplify HHS system requirements for data capture. We further note that newly practicing EPs have the ability to apply for a hardship exception from the Secretary under § 495.102(d)(4)(ii), which provides for an exception from the payment adjustments for the 2 years after they begin practicing. We propose amendments to the definition of “EHR reporting period for a payment adjustment year” under § 495.4 to reflect these proposals. We welcome public comments on this proposal.

3. Exception to the Application of the Payment Adjustment to EPs in CY 2017 and Subsequent Years

As previously discussed, sections 1848(a)(7)(B) of the Act provides that the Secretary may, on a case-by-case basis, exempt an EP from the application of the payment adjustment in CY 2015 and subsequent calendar years if the Secretary determines that compliance with the requirements for being a meaningful EHR user will result in a significant hardship, such as an EP who practices in a rural area without sufficient internet access. As provided by the statute, the exception is subject to annual renewal, but in no case may an EP be granted an exception for more than 5 years. The statute does not require the Secretary to grant exceptions. However, as we stated in the

Stage 2 final rule at 77 FR 54097, we believe that certain circumstances evidence the existence of a hardship, thereby justifying the need for an exception by the Secretary. Therefore, in the Stage 2 final rule, we finalized various types of hardship exceptions that EPs could apply for, which included insufficient internet access, newly practicing EPs, extreme circumstances outside of an EP’s control, lack of control over the availability of CEHRT for EPs practicing in multiple locations, lack of face-to-face patient interactions and lack of need for follow-up care, and certain primary specialties. For further discussion of the hardship exceptions, we refer readers to the Stage 2 final rule at 77 FR 54097 through 54101 and 42 CFR 495.102(d)(4).

In this Stage 3 proposed rule, we propose no changes to the types of exceptions previously finalized for EPs, nor do we propose any new types of exceptions for 2017 and subsequent years. Accordingly, we propose that the exceptions continue as previously finalized.

4. Statutory Basis for Payment Adjustments and Hardship Exceptions for Eligible Hospitals

Section 1886(b)(3)(B)(ix)(I) of the Act, as amended by section 4102(b)(1) of the HITECH Act, provides for an adjustment to the applicable percentage increase to the IPPS payment rate for those eligible hospitals that are not meaningful EHR users for the associated EHR reporting period for a payment adjustment year, beginning in FY 2015. Specifically, section 1886(b)(3)(B)(ix)(I) of the Act provides that, for FY 2015 and each subsequent fiscal year, an eligible hospital that is not “a meaningful EHR user . . . for an EHR reporting period” will receive a reduced update to the IPPS standardized amount. This reduction applies to “three-quarters of the percentage increase otherwise applicable” prior to the application of statutory adjustments under sections 1886(b)(3)(B)(viii), 1886(b)(3)(B)(xi), and 1886(b)(3)(B)(xii) of the Act, or three-quarters of the applicable market basket update. The reduction to three-quarters of the applicable update for an eligible hospital that is not a meaningful EHR user will be “33⅓ percent for FY 2015, 66⅔ percent for FY 2016, and 100 percent for FY 2017 and each subsequent FY.” In other words, for eligible hospitals that are not meaningful EHR users, the Secretary must reduce the applicable percentage increase (prior to the application of other statutory adjustments) by 25 percent (33⅓ of 75 percent) in FY 2015,

50 percent (66 $\frac{2}{3}$ percent of 75 percent) in FY 2016, and 75 percent (100 percent of 75 percent) in FY 2017 and subsequent years. Section 4102(b)(1)(B) of the HITECH Act also provides that the reduction shall apply only with respect to the fiscal year involved and the Secretary shall not take into account such reduction in computing the applicable percentage increase for a subsequent fiscal year.

Section 1886(b)(3)(B)(ix)(II) of the Act, as amended by Section 4102(b)(1) of the HITECH Act, provides that the Secretary may, on a case-by-case basis, exempt a hospital from the application of the applicable percentage increase adjustment for a fiscal year if the Secretary determines that requiring such hospital to be a meaningful EHR user will result in a significant hardship, such as in the case of a hospital in a rural area without sufficient internet access. This section also provides that such determinations are subject to annual renewal, and that in no case may a hospital be granted an exception for more than 5 years.

5. Applicable Market Basket Update Adjustment for Eligible Hospitals That Are Not Meaningful EHR Users for FY 2019 and Subsequent Fiscal Years

Section 412.64(d) of the regulations sets forth the adjustment to the percentage increase in the market basket index for those eligible hospitals that are not meaningful EHR users for the EHR reporting period for a payment year, beginning in FY 2015.

6. EHR Reporting Period for Determining Whether a Hospital Is Subject to the Market Basket Update Adjustment for FY 2018 and Subsequent Fiscal Years

Section 1886(b)(3)(B)(ix)(IV) of the Act makes clear that the Secretary has discretion to specify as the EHR reporting period “any period (or periods)” that will apply “with respect to a fiscal year.” In the Stage 2 final rule at 77 FR 54104 through 54105, we finalized the applicable EHR reporting period for purposes of determining whether an eligible hospital is subject to the payment adjustment.

As with EPs, we finalized that the EHR reporting period for the payment adjustment year for eligible hospitals will begin and end prior to the year of the payment adjustment. We finalized under § 495.4 of the regulations that for eligible hospitals, the EHR reporting period for a payment adjustment year is the full federal fiscal year that is 2 years before the payment adjustment year. We established this policy beginning with the FY 2015 payment adjustment year

and continuing in subsequent years. For example, the full federal fiscal year of 2015 would be the EHR reporting period for the FY 2017 payment adjustment year. However, in this Stage 3 proposed rule, beginning in 2017, we propose to change the EHR reporting period for a payment adjustment year for eligible hospitals from a fiscal year basis to a calendar year basis. Specifically, we propose to revise the definition of “EHR reporting period for a payment adjustment year” under § 495.4 such that the EHR reporting period for a payment adjustment year for an eligible hospital would be the full calendar year that is 2 years before the payment adjustment year. For example, the entire CY 2017 would be the EHR reporting period used to determine whether the payment adjustment would apply for an eligible hospital for FY 2019. This change would apply beginning with the CY 2017 EHR reporting period for purposes of the FY 2019 payment adjustment year, and continue to apply in subsequent years. We note that eligible hospitals would have ample time to adjust to the new calendar year reporting timeframe given that under our current policy, the EHR reporting period occurs prior to the payment adjustment year. We further believe that aligning all providers, including eligible hospitals, to a calendar year EHR reporting timeframe for purposes of the payment adjustment, would simplify reporting for all providers, especially for larger providers with diverse systems and groups. In addition, placing all providers, including eligible hospitals, onto a calendar year timeframe would further simplify HHS system requirements for data capture and would move the EHR Incentive Program another step closer to alignment with various CMS quality reporting programs. We welcome comments on this proposal.

Further, in the Stage 2 final rule, we finalized an exception to the general rule of a full federal fiscal year EHR reporting period for eligible hospitals that have never successfully attested to meaningful use. Stated generally, under this exception, for an eligible hospital that is demonstrating meaningful use for the first time, the EHR reporting period for a payment adjustment year is any continuous 90-day period. For a full description of this exception, including limitations on when the continuous 90-day period must occur in relation to the payment adjustment year and the deadlines for registration and attestation, we refer readers to the definition of “EHR reporting period for a payment adjustment year” under

§ 495.4 of the regulations and the discussion in the Stage 2 final rule (77 FR 54104 and 54105).

However, in this Stage 3 proposed rule, we propose to eliminate this exception for eligible hospitals that are new meaningful EHR users beginning with the EHR reporting period in 2017, with a limited exception for Medicaid eligible hospitals demonstrating meaningful use for the first time. As explained previously, we propose that for eligible hospitals that have successfully demonstrated meaningful use in a prior year as well as those that have not, the EHR reporting period for a payment adjustment year would be the full calendar year that is 2 years before the payment adjustment year. For example, for all eligible hospitals, the full CY 2017 would be the EHR reporting period for the FY 2019 payment adjustment year. This policy would continue to apply in subsequent years.

Though, as discussed in sections II.A.1.a. and II.F.1. of this proposed rule, for Medicaid eligible hospitals demonstrating meaningful use for the first time, we are proposing to maintain a 90-day EHR reporting period for the first payment year based on meaningful use. We recognize that these eligible hospitals may be subject to payment adjustments under Medicare if they fail to demonstrate meaningful use, and thus we propose that the same 90-day EHR reporting period used for the Medicaid incentive payment would also apply for purposes of the Medicare payment adjustment for the payment adjustment year 2 years after the calendar year in which the provider demonstrates meaningful use. We note under our current policy, if an eligible hospital has never successfully demonstrated meaningful use, the EHR reporting period for a payment adjustment year is any continuous 90-day period that both begins in the federal fiscal year 1 year before the payment adjustment year and ends at least 3 months before the end of such prior year. We do not propose to maintain this policy, and thus for Medicaid eligible hospitals that are new meaningful EHR users, the 90-day EHR reporting period for a payment adjustment year must occur within the calendar year that is 2 years before the payment adjustment year. These proposals for Medicaid eligible hospitals would apply beginning with the EHR reporting period in CY 2017.

We provide the following example:
Example A: If an eligible hospital has never successfully demonstrated meaningful use prior to CY 2017 and demonstrates under the Medicaid EHR

Incentive Program that it is a meaningful EHR user for the first time in CY 2017, the EHR reporting period for the Medicaid incentive payment would be any continuous 90-day period within CY 2017. The same 90-day period would also serve as the EHR reporting period for the FY 2019 payment adjustment year under Medicare. This 90-day period would not serve as the EHR reporting period for the FY 2018 payment adjustment year under Medicare even if the eligible hospital registers for and attests to meaningful use by July 1, 2017. The eligible hospital would have to demonstrate meaningful use for an EHR reporting period of the full CY 2018 to earn an incentive payment under Medicaid for the 2018 payment year and avoid the payment adjustment under Medicare for the FY 2020 payment adjustment year.

Like our proposal to move eligible hospitals to a calendar year timeframe, we believe that removing the continuous 90-day EHR reporting period for most eligible hospitals would simplify reporting for providers, especially those hospitals with diverse groups and systems. In addition, eliminating the 90-day EHR reporting period would move the EHR Incentive Program one step closer to alignment within the program and with CMS quality reporting programs and would simplify HHS system requirements for data capture. Therefore, moving eligible hospitals to a calendar year EHR reporting period for the payment adjustment years, as well as requiring all providers (EPs and hospitals) to report based on the same full year calendar timeframe would accomplish these goals and be responsive to prior public comments asking us to simplify the EHR Incentive Program.

We propose amendments to the definition of "EHR reporting period for a payment adjustment year" under § 495.4 to reflect these proposals.

We note that hospitals that are eligible under both the Medicaid and Medicare incentive programs, and that are attesting for the Medicaid program, do not need to separately attest in the Medicare program in 2017 and subsequent years, because the statute does not allow for Medicare EHR incentive payments to eligible hospitals after FY 2016. If a hospital eligible under both programs is demonstrating meaningful use for the first time, and using a continuous 90-day EHR reporting period under the Medicaid program, it could attest for the Medicaid program only, and still avoid the Medicare payment adjustment that is 2 years after the calendar year in which

the EHR reporting period occurs. However, if a hospital eligible under both programs chooses also to attest for the Medicare program, it would be required to complete an EHR reporting period of 1 full calendar year to avoid the Medicare payment adjustment that is 2 years after that calendar year.

We welcome public comments on these proposals.

7. Exception to the Application of the Market Basket Update Adjustment to Hospitals in FY 2019 and Subsequent Fiscal Years

As stated previously, section 1886(b)(3)(B)(ix)(II) of the Act, as amended by section 4102(b)(1) of the HITECH Act, provides that the Secretary, may, on a case-by-case basis, exempt a hospital from the application of the applicable percentage increase payment adjustment for a fiscal year if the Secretary determines that compliance with the requirements for being a meaningful EHR user will result in a significant hardship, such as an eligible hospital located in a rural area without sufficient internet access. Section 1886(b)(3)(B)(ix)(III) also provides that the exception is subject to annual renewal, but in no case may a hospital be granted an exception for more than 5 years. The Secretary's hardship exception authority is discretionary.

As we explained in the Stage 2 final rule at 77 FR 54105 through 54106, we believe that certain circumstances may constitute a hardship that would warrant the Secretary's use of the exception authority. Therefore, in the Stage 2 final rule, we finalized various types of hardship exceptions for which eligible hospitals may apply, which included lack of insufficient internet access, extreme circumstances outside of a hospital's control, and the establishment of new hospitals. For further discussion of the hardship exceptions, we refer readers to the Stage 2 final rule at 77 FR 54105 through 54108 as well as 42 CFR 412.64(d)(4).

In this Stage 3 proposed rule, we propose no changes to the types of exceptions previously finalized for eligible hospitals, nor do we propose any new exceptions for eligible hospitals. Accordingly, for Stage 3, we propose to continue the hardship exceptions for 2017 and subsequent years as previously finalized.

8. Statutory Basis for Payment Adjustments to CAHs

Section 4102(b)(2) of the HITECH Act amended section 1814(l) of the Act to include an adjustment to a CAH's Medicare reimbursement for inpatient

services if the CAH is not a meaningful EHR user for an EHR reporting period. The adjustment will be made for cost reporting periods that begin in FY 2015, FY 2016, FY 2017, and each subsequent FY thereafter. Specifically, sections 1814(l)(4)(A) and (B) of the Act provide that, if a CAH does not demonstrate meaningful use of CEHRT for an applicable EHR reporting period, then for a cost reporting period beginning in FY 2015, the CAH's reimbursement shall be reduced from 101 percent of its reasonable costs to 100.66 percent of reasonable costs. For a cost reporting period beginning in FY 2016, its reimbursement would be reduced to 100.33 percent of its reasonable costs. For a cost reporting period beginning in FY 2017 and each subsequent fiscal year, its reimbursement would be reduced to 100 percent of reasonable costs.

However, as provided for eligible hospitals, a CAH, may, on a case-by-case basis, be granted an exception from this adjustment if CMS or its Medicare contractor determines, on an annual basis, that a significant hardship exists, such as in the case of a CAH in a rural area without sufficient internet access. However, in no case may a CAH be granted this exception for more than 5 years.

9. Reduction of Reasonable Cost Reimbursement in FY 2015 and Subsequent Years for CAHs That Are Not Meaningful EHR Users

a. Applicable Reduction of Reasonable Cost Payment Reduction in FY 2015 and Subsequent Years for CAHs That Are Not Meaningful EHR Users

In the Stage 1 final rule (75 FR 44564), we finalized the regulations regarding the CAH adjustment at § 495.106(e) and § 413.70(a)(6).

b. EHR Reporting Period for Determining Whether a CAH Is Subject to the Applicable Reduction of Reasonable Cost Payment in FY 2015 and Subsequent Years

In Stage 2, we amended the definition of the EHR reporting period that would apply for purposes of the payment adjustment for CAHs under § 495.4 (77 FR 54109 and 54110). For CAHs, this is the full federal fiscal year that is the same as the payment adjustment year (unless a CAH is in its first year of demonstrating meaningful use, in which case a continuous 90-day EHR reporting period within the payment adjustment year would apply). The adjustment applies based upon the cost reporting period that begins in the payment adjustment year (that is, FY 2015 and

thereafter). Thus, if a CAH is not a meaningful EHR user for FY 2015, and thereafter, then the payment adjustment is applied to the CAH's reasonable costs incurred in a cost reporting period that begins in the affected fiscal year as described in § 413.70(a)(6)(i). We further finalized that CAHs submit their attestations on meaningful use by November 30 of the following fiscal year. For example, if a CAH is attesting that it was a meaningful EHR user for FY 2015, the attestation must be submitted no later than November 30, 2015. Such an attestation or lack thereof, will then affect interim payments to the CAH made after December 1 of the applicable fiscal year. If the cost reporting period ends prior to December 1 of the applicable fiscal year, then any applicable payment adjustment will be made through the cost report settlement process.

Under this Stage 3 proposed rule, we are proposing a change to the EHR reporting period that would apply for the payment adjustments for CAHs, beginning with the FY 2017 payment adjustment year. First, similar to what we proposed for eligible hospitals previously, we propose that the EHR reporting period for a payment adjustment year for CAHs would be a full calendar year, rather than a full federal fiscal year. We propose the EHR reporting period for a payment adjustment year would be the calendar year that overlaps the last 3 quarters of the federal fiscal year that is the payment adjustment year. For example, in order for a CAH to avoid application of the adjustment to its reasonable costs incurred in a cost reporting period that begins in FY 2017, the CAH must demonstrate it is a meaningful EHR user for an EHR reporting period of the full CY 2017. This proposed change would mean that the EHR reporting period would no longer precisely align with the payment adjustment year. We propose amendments to the definition of "EHR reporting period for a payment adjustment year" under § 495.4 to reflect these proposals.

In the Stage 2 final rule, we note the process for the implementation of a payment adjustment to CAH cost reports in relation to the EHR reporting period attestation deadline (77 FR 54109 and 54110). Under our Stage 3 proposal, we would need to move the CAH attestation deadline in order to accommodate the change to a calendar year-based EHR reporting period. Therefore, we propose to move the CAH attestation deadline to the last day in February following the end of the EHR reporting period as we currently allow for EPs. Any accounting shifts that occur as a result from the

change to a calendar year-based EHR reporting period can be accommodated through the cost reporting and settlement process. The CAH must attest no later than 2 months (February 28 or February 29 if applicable) following the close of the EHR reporting period at the end of each calendar year to avoid the payment adjustment. Such an attestation or lack thereof, will then affect interim payments to the CAH made after March 1 of the applicable federal fiscal year. If the cost reporting period ends prior to March 1 of the applicable fiscal year, then any applicable payment adjustment will be made through the cost report settlement process.

We are proposing this change to the EHR reporting period for the payment adjustment year to further align most providers to a calendar year-based EHR reporting period. We believe that the change to calendar year reporting for CAHs is feasible given that the cost reporting and cost settlement processes is unique to CAHs under the Medicare EHR Incentive Program. Unlike eligible hospitals or EPs, who use a claims processing system to determine the payment adjustment under the Medicare EHR Program, CAHs are required to file an annual Medicare cost report that is typically for a consecutive 12-month period. The cost report reflects the inpatient statistical and financial data that forms the basis of the CAH's Medicare reimbursement. Interim Medicare payment may be made to the CAH during the cost reporting period based on the previous year's data. Cost reports are filed with the CAH's Medicare contractor after the close of the cost reporting period, and the data on the cost report are subject to the reconciliation and settlement process prior to a final Medicare payment being made. The proposed change to a calendar year EHR reporting period for CAHs would not significantly impact the ability to implement the payment adjustments in the cost report reconciliation process for either CAHs or CMS. It would only shift the potential date where the reconciliation of any payment adjustment in the cost reporting process may occur. These payments would still be subject to the reconciliation and settlement process prior to a final Medicare payment being made.

For example, currently CAHs must file their attestations on meaningful use by November 30 of the federal fiscal year following the close of the federal fiscal year in which the EHR reporting period occurs. Under our current system, if a CAH is attesting that it was a meaningful EHR user for FY 2015, the

attestation must be submitted not later than November 30, 2015. A payment adjustment applied if the CAH does not successfully attest would affect interim payment to the CAH made after December 1 of 2015. If the cost reporting period ends prior to December 1, 2015, then any applicable payment adjustment will be made under the cost reporting settlement process.

In an example of a similar scenario under the new proposal, a CAH that does not successfully demonstrate meaningful use based on a calendar year EHR reporting period in 2017 (January 1, 2017 through December 31, 2017) would be subject to a payment adjustment applied to its reasonable costs incurred in the cost reporting period beginning in FY 2017 (October 1, 2017 through September 30, 2018). To avoid the payment adjustment in this example, the CAH must attest no later than February 28, 2018 to demonstrate meaningful use for an EHR reporting period in 2017. If the CAH does not attest by February 28, 2018, a payment adjustment would then affect interim payments to the CAH made after March 1, 2018. If the cost reporting period ends prior to March 1, 2018, then any applicable payment adjustment would be made through the cost report settlement process. We note that this is reflective of a similar policy in the Stage 2 final rule addressing the process for CAH payment adjustments with an attestation deadline of November 30 in a given year and direct readers to 77 FR 54110 for further information on this policy.

Second, as noted previously, and outlined in the definition of "EHR reporting period for a payment adjustment year" under § 495.4, we established an exception for first-time CAH meaningful EHR users. Under our current policy, if a CAH is demonstrating it is a meaningful EHR user for the first time in the payment adjustment year, the applicable EHR reporting period is any continuous 90-day period within the federal fiscal year that is the payment adjustment year.

For this Stage 3 proposed rule, we propose to eliminate this exception for CAHs that are new meaningful EHR users beginning with the EHR reporting period in 2017, with a limited exception for CAHs demonstrating meaningful use for the first time under the Medicaid EHR Incentive Program. As discussed in II.A.1.a. and II.F.1. of this proposed rule, for CAHs that demonstrate meaningful use for the first time under Medicaid, we are proposing to maintain a 90-day EHR reporting period for the first payment year based on meaningful use. We recognize that these CAHs may be

subject to payment adjustments under Medicare if they fail to demonstrate meaningful use, and thus we propose that the same 90-day EHR reporting period used for the Medicaid incentive payment would also apply for purposes of the Medicare payment adjustment.

We propose amendments to the definition of “EHR reporting period for a payment adjustment year” under § 495.4 to reflect these proposals. Example A: If a CAH has never successfully demonstrated meaningful use prior to CY 2017 and demonstrates under the Medicaid EHR Incentive Program that it is a meaningful EHR user for the first time in CY 2017, the EHR reporting period for the Medicaid incentive payment would be any continuous 90-day period within CY 2017. The same 90-day period would also serve as the EHR reporting period for the FFY 2017 payment adjustment year under Medicare.

Like our proposal to move CAHs to a calendar year timeframe, we believe that removing the continuous 90-day EHR reporting period for most CAHs would simplify reporting for providers, especially those CAHs with diverse groups and systems. In addition, eliminating the 90-day EHR reporting period would move the EHR Incentive Program one step closer to alignment within the program and with CMS quality reporting programs, and would simplify HHS system requirements for data capture. Therefore, moving CAHs to a calendar year EHR reporting period for the payment adjustment year, as well as requiring most providers (EPs, CAHs, and eligible hospitals) to report based on the same full year calendar timeframe would accomplish these goals and be responsive to prior public comments asking us to simplify the EHR Incentive Program.

We welcome public comments on these proposals.

10. Administrative Review Process of Certain Electronic Health Record Incentive Program Determinations

In the Stage 2 final rule (77 FR 54112 through 54113), we discussed an administrative appeals process for both Stages 1 and 2 of meaningful use. We believe this appeals process is primarily procedural and does not need to be specified in regulation. We have developed guidance on the appeals process, which is available on our Web site at www.cms.gov/EHRIncentivePrograms. We propose no changes in this proposed rule and intend to continue to specify the appeals process in guidance available on our Web site.

E. Medicare Advantage Organization Incentive Payments

We are not proposing any changes to the existing policies and regulations for Medicare Advantage (MA) organizations. Our existing policies and regulations include provisions concerning the EHR incentive payments to qualifying MA organizations and the payment adjustments for 2015 and subsequent MA payment adjustment years. (For more information on MA organization incentive payments, we refer readers to the final rules for Stages 1 and 2 (75 FR 44468 through 44482 and 77 FR 54113 through 54119).)

F. The Medicaid EHR Incentive Program

The proposals discussed in sections II.F.1. through II.F.3. of this proposed rule would be applicable upon the effective date of the final rule, not when Stage 3 of meaningful use of certified EHR technology begins, unless otherwise indicated.

1. EHR Reporting Period for First Year of Meaningful Use

We are proposing amendments to the definitions of “EHR reporting period” and “EHR reporting period for a payment adjustment year” in § 495.4 to shift the EHR reporting periods for eligible hospitals and CAHs to periods that are based on the calendar year, not the federal fiscal year, and to establish a full calendar year as the EHR reporting period or EHR reporting period for a payment adjustment year for almost all providers beginning in 2017. However, we are also proposing a limited exception under which Medicaid EPs and eligible hospitals demonstrating meaningful use for the first time could use any continuous 90-day EHR reporting period within the calendar year. This EHR reporting period for Medicaid providers demonstrating meaningful use for the first time would apply both for purposes of receiving an incentive payment in the Medicaid program and for purposes of avoiding the payment adjustment under the Medicare program for the payment adjustment year that is two years after the calendar year in which the provider first demonstrates meaningful use for an EHR reporting period. Under this proposal, Medicaid EPs and eligible hospitals would have an EHR reporting period of any continuous 90-day period in the calendar year that is the payment year, for their first payment year based on meaningful use, beginning in 2017. We note that hospitals that are eligible under both the Medicaid and Medicare incentive programs, and that are attesting for the Medicaid program, do

not need to separately attest in the Medicare program in 2017 and subsequent years, because the statute does not allow for Medicare EHR incentive payments to eligible hospitals after FY 2016. If a hospital eligible under both programs is demonstrating meaningful use for the first time, and using a continuous 90-day EHR reporting period under the Medicaid program, it could attest for the Medicaid program only, and still avoid the Medicare payment adjustment that is 2 years after the calendar year in which the EHR reporting period occurs. However, if a hospital eligible under both programs chooses also to attest for the Medicare program, it would be required to complete an EHR reporting period of 1 full calendar year to avoid the Medicare payment adjustment that is 2 years after that calendar year. We note that, consistent with the other proposed amendments to § 495.4 discussed previously, this proposal would change the EHR reporting period for eligible hospitals from one that is based on the federal fiscal year to one that is based on the calendar year, beginning in 2017. For further discussion of the relationship between the 90-day EHR reporting period under the Medicaid EHR Incentive Program and the payment adjustments under Medicare, we refer readers to section II.D. of this proposed rule.

This policy would allow Medicaid providers flexibility in their first year of demonstrating meaningful use. It also would reduce the burden on states to implement significant policy and system changes in preparation for Stage 3, as the 90-day period for the first year of meaningful use is consistent with our previous policies and meaningful use timelines.

2. Reporting Requirements

a. State Reporting on Program Activities

As discussed in section II.A.1.c.(1).(b).(iii). of this proposed rule, we are adding a new provision at § 495.316(d)(2)(iii) to provide states with flexibility regarding the Stage 3 public health and clinical data registry reporting objective.

We also propose to amend § 495.316(c), as well as add a new paragraph § 495.316(f), to formalize the process of how states report to us annually on the providers that have attested to adopt, implement, or upgrade (AIU), or that have attested to meaningful use. Under this proposal, states would follow a structured submission process, in the manner prescribed by CMS, which would include a new annual reporting

deadline. We propose to require states to submit annual reports to CMS within 45 days of the end of the second quarter of each federal fiscal year.

We propose to regularize the timing of the annual reporting process described in § 495.316 to ensure more timely annual reports and allow for clearer communication to states on when the reports should be submitted to CMS. In addition, CMS and states would be able to more effectively track the progress of states' incentive program implementation and oversight as well as provider progress in achieving meaningful use. Predictable deadlines for annual reporting would permit CMS and the states to more quickly compare and assess overall program impact each year.

We are also considering changes to the data that the annual reporting requirements outlined in § 495.316(d) require states to include in their annual reports. Specifically, we are considering whether to remove the requirement that states report information about practice location for providers that qualify for incentive payments on the basis of having adopted, implemented, or upgraded certified EHR technology or on the basis of demonstrating they are meaningful users of certified EHR technology. While we believe that this data is useful to both CMS and the states for program implementation purposes, we believe the benefits of including it in state reports might be outweighed by the burdens to states of reporting it. Therefore, we are seeking more information on state burdens and costs associated with complying with this requirement. We solicit comments both on the burdens associated with the requirement to report practice location information for providers that receive incentive payments through the Medicaid EHR Incentive Program, and on the benefits of including this information in state reports.

We propose to amend § 495.352 to formalize the process of how states submit quarterly progress reports on implementation and oversight activities and to specify the elements that should be included in the quarterly reports. Under this proposal, states would follow a structured submission process, in the manner prescribed by CMS. We propose that states would report on the following activities: State system implementation dates; provider outreach; auditing; state-specific SMHP tasks; state staffing levels and changes; the number and type of providers that qualified for an incentive payment on the basis of demonstrating that they are meaningful EHR users of certified EHR technology and the amounts of

incentive payments; and the number and type of providers that qualified for an incentive payment on the basis of having adopted, implemented, or upgraded certified EHR technology and the amounts of incentive payments.

We propose these changes to the quarterly reporting process described in § 495.352 so that CMS and states can better track state implementation and oversight activity progress in a way that would permit CMS and the states to compare overall programmatic and provider progress. We also expect that streamlined and enhanced quarterly progress reporting would lead to an improvement in overall data quality that would help inform future meaningful use activity across states.

We would like to include a deadline for states' quarterly reporting under the proposed amendments to § 495.352, and are considering requiring states to submit quarterly progress reports to CMS within 30 days after the end of each federal fiscal year quarter. We believe that a set deadline would improve timeliness and communication, but we do not want to set a deadline that is overly burdensome for a report that must be submitted quarterly. We seek public comment on the deadline we are considering.

b. State Reporting on Meaningful EHR Users

Starting in FY 2015 for eligible hospitals and CY 2015 for EPs, providers that fail to demonstrate meaningful use for an applicable EHR reporting period will be subject to downward payment adjustments under Medicare. As discussed in the Stage 2 final rule (77 FR 54094), EPs who are meaningful EHR users under the Medicaid EHR Incentive Program for an applicable EHR reporting period will be considered meaningful EHR users for that period for purposes of avoiding the Medicare payment adjustments. Currently, hospitals eligible for both Medicaid and Medicare incentive payments attest in both the Medicare and Medicaid systems to earn an incentive payment in both programs. The statute does not authorize Medicare EHR incentive payments to eligible hospitals after FY 2016. To avoid duplicative reporting, hospitals eligible under both programs will not be required to attest in both programs beginning in 2017. Therefore, we must have accurate and timely data from states regarding both EPs and eligible hospitals that have successfully demonstrated meaningful use for each payment year to ensure that meaningful EHR users in the Medicaid EHR Incentive Program are appropriately

exempted from the Medicare payment adjustment for the applicable payment adjustment year. This additional reporting is necessary because the electronic data currently contained in the National Level Repository are insufficient to determine which Medicaid providers should be exempted from the Medicare payment adjustments in an accurate and timely manner. Accordingly, we propose to add new paragraphs (g) and (h) to § 495.316 to require that states submit reports on a quarterly basis that identify certain providers that attested to meaningful use through the Medicaid EHR Incentive Program for each payment year. Under this proposal, states would submit quarterly reports for Medicaid EPs and eligible hospitals that successfully attest to meaningful use for each payment year.

We propose that states would report quarterly, in the manner prescribed by CMS, information on each provider that successfully attests to meaningful use, regardless of whether the provider has been paid yet. The report would be required to specify the Medicaid state and payment year. For each EP or eligible hospital listed in the report, the state would also specify the Payment Year Number, the NPI for EPs and the CCN for eligible hospitals, the Attestation Submission Date, the State Qualification (as either meaningful use or blank), and the State Qualification Date (the beginning date of the reporting period in which successful meaningful use attestation was achieved by the EP or eligible hospital). The EP or eligible hospital's "payment year number" refers to the number of years that the provider has been paid in the EHR Incentive Program; so, for example, this would be "2" for the 2014 payment year if the provider received payments for 2013 and 2014. States would have this data, even for providers that have previously received an incentive payment through the Medicare EHR Incentive Program. If the state is reporting a disqualification, then the state would leave the State Qualification field blank. If applicable, in the cases of EPs or eligible hospitals previously identified as meaningful EHR users, the state would be required to specify the State Disqualification and State Disqualification Date (that is, the beginning date of the EHR reporting period during which an EP or eligible hospital was found not to meet the definition of a meaningful EHR user).

Under this proposal, states would submit this information beginning with payment year 2013 data. The reports would cover back to the 2013 payment year because that would be the EHR

reporting period for the 2015 Medicare payment adjustment year under § 495.4. Providers that successfully attested to meaningful use for 2013 would be exempt from the Medicare payment adjustment in 2015.

Under this proposal, states would not be required to include information about certain providers in their reports. We recognize that several provider types that are eligible for the Medicaid EHR Incentive Program are not subject to the Medicare payment adjustments. Accordingly, states would not be required to report on those EPs who are eligible for the Medicaid EHR Incentive Program on the basis of being a nurse practitioner, certified nurse-midwife, or physician assistant.

3. Clinical Quality Measurement for the Medicaid Program

States are, and will continue in Stage 3 to be, responsible for determining whether and how electronic reporting of CQMs would occur, or whether they wish to allow reporting through attestation. This is consistent with our policy in the Stage 2 final rule (77 FR 54075). If a state does require electronic reporting, the state is responsible for sharing the details on the process with its provider community. We anticipate that whatever means states have deployed for capturing Stages 1 and 2 clinical quality measures electronically would be similar for reporting in 2017 and subsequent years. However, we note that subject to our prior approval, this is within the states' purview. States that wish to establish the method and requirements for electronically reporting would continue to be required to do so through the SMHP submission, subject to our prior approval.

To further our goals of alignment and avoiding duplicative reporting across quality reporting programs, we would recommend that states include a narrative in their SMHP for CY 2017 describing how their proposed meaningful use CQM data submission strategy aligns with their State Medicaid Quality Strategy and report which certified EHR technology requirements they mandate for eCQM reporting.

For more information on requirements around the State Medicaid Quality Strategy, see <http://medicaid.gov/Federal-Policy-Guidance/Downloads/SHO-13-007.pdf>.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is

submitted to the Office of Management and Budget (OMB) for review and approval. In order to evaluate fairly whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The following is a discussion of the requirements contained in this proposed regulation that we believe are subject to PRA and collection of information requirements (ICRs). The projected numbers of EPs, eligible hospitals, and CAHs, MA organizations, MA EPs and MA-affiliated hospitals are based on the numbers used in the impact analysis assumptions as well as estimated federal costs and savings in the section V.C. of this proposed rule. The actual burden would remain constant for all of Stage 3 as EPs, eligible hospitals, and CAHs would only need to attest that they have successfully demonstrated meaningful use in 2017 and annually thereafter. The only variable from year-to-year in Stage 3 would be the number of respondents, as noted in the impact analysis assumptions. For the purposes of this analysis, we are focusing only on 2017, the first year in which a provider may participate in Stage 3 of the Medicare EHR Incentive Program. We do not believe the burden for EPs, eligible hospitals, and CAHs participating in Stages 1 and 2 prior to 2017 would be different from the Agency Information Collection Activities (75 FR 65354) based on this proposed rule. Beginning in 2012, Medicare EPs, eligible hospitals, and CAHs have the option to electronically report their clinical quality measures through the respective electronic reporting pilots. For eligible hospitals and CAHs, the burden is discussed in the CY 2012 Hospital Outpatient Prospective Payment System final rule with comment period (76 FR 73450 through 73451).

As discussed in section I.A.1.a. of this proposed rule, Stage 3 is intended to build on Stages 1 and 2 with a focus on advanced use of certified EHR technology to promote improved patient outcomes while assuring that the framework is flexible and does not hinder innovation. In this proposed rule, the definition of meaningful use

with associated reporting requirements would replace all prior definitions and requirements beginning in 2018. At that point, all eligible providers would be required to report only Stage 3 requirements on an annual basis. For 2017, providers may simply repeat their current status at Stage 1 or Stage 2, or move on to Stage 3. The same reporting time would apply to all providers. Consequently, the proposed ICRs reflect the provider burden associated with complying with and reporting of Stage 3 requirements beginning in 2017 and each subsequent year.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. ICR Regarding Demonstration of Meaningful Use Criteria (§ 495.6, § 495.7 and § 495.8)

In § 495.7 we propose that to successfully demonstrate meaningful use of certified EHR technology for Stage 3, an EP, eligible hospital, or CAH (collectively referred to as "provider" in this section) must attest, through a secure mechanism in a specified manner, to the following during the EHR reporting period—

- The provider used certified EHR technology and specified the technology was used; and
- The provider satisfied each of the applicable objectives and associated measures in § 495.7.

In § 495.8, we stipulate that providers must also successfully report the clinical quality measures selected by CMS to CMS or the states, as applicable. We estimate that the certified EHR technology adopted by the provider captures many of the objectives and associated measures and generate automated numerator and denominator information where required, or generate automated summary reports. We also expect that the provider would enable the functionality required to complete the objectives and associated measures that require the provider to attest that they have done so.

We propose that there would be 5 objectives and 10 measures that would require an EP to enter numerators and denominators during attestation. Eligible hospitals and CAHs would have to attest they have met 5 objectives and 10 measures that would require numerators and denominators. For objectives and associated measures requiring a numerator and denominator in this proposed rule, we limit our estimates to actions taken in the presence of certified EHR technology. We do not anticipate a provider would

maintain two recordkeeping systems when certified EHR technology is present. Therefore, we assume that all patient records that would be counted in the denominator would be kept using certified EHR technology. We expect it would take an individual provider or designee approximately 10 minutes to attest to each meaningful use objective and associated measure that requires a numerator and denominator to be generated. The security risk assessment and its associated measure would not require a numerator and denominator and we would expect it would take an individual provider or designee approximately 6 hours to complete. The clinical decision support and active engagement with a public health agency measures would take an eligible professional, eligible hospital or critical access hospital 1 minute each to report each CDS intervention or registry.

We propose that EPs would be required to report on a total of 8 objectives and 16 associated measures. For the purpose of this proposed collection of information, we assumed that all eligible providers would comply with the requirements of meaningful use Stage 3. We propose that eligible hospitals and CAHs would be required to report on a total of 8 objectives and 17 associated measures. We estimated the total annual cost burden for all eligible hospitals and CAHs to attest to EHR technology, meaningful use objectives and associated measures, and electronically submit the clinical quality measures would be \$2,135,204 (4,900 eligible hospitals and CAHs × 6 hours 52 minutes × \$63.46 (mean hourly rate for lawyers based on May 2013 BLS data)). We estimate the total annual cost burden for all EPs to attest to EHR technology, meaningful use objectives

and associated measures, and electronically submit the clinical quality measures would be \$385,834,395 (609,100 EPs × 6 hours 52 minutes × \$92.25 (mean hourly rate for physicians based on May 2013 BLS) data).

In this proposed rule, there are 5 objectives that would require an EP to enter numerators and denominators during attestation. Eligible hospitals and CAHs would have to attest that they have met five objectives that require numerators and denominators. For objectives and associated measures requiring a numerator and denominator, we limit our estimates to actions taken in the presence of certified EHR technology. We do not anticipate a provider would maintain two recordkeeping systems when certified EHR technology is present. Therefore, we assume that all patient records that would be counted in the denominator would be kept using certified EHR technology. We expect it would take an individual provider or designee approximately 10 minutes to attest to each meaningful use objective and associated measure that requires a numerator and denominator to be generated, as well as each CQM for providers attesting in their first year of the program.

Additionally, providers would be required to report they have completed objectives and associated measures that require a “yes” or “no” response during attestation. For EPs, there are three objectives that would require a “yes” or “no” response during attestation. As discussed previously, the associated measures are that EPs are required to conduct a security risk analysis, report to three registries to fulfill the public health objective, and must implement at least five clinical decision support

interventions. For eligible hospitals and CAHs, there are three objectives that would require a “yes” or “no” response during attestation. The associated measures for eligible hospitals and CAHs require the provider to conduct a security risk analysis, report to four registries to fulfill the public health objective and must implement at least five clinical decision support interventions. We estimate each of these measures would take 1 minute to report.

Providers would also be required to attest that they are protecting electronic health information. We estimate completion of the analysis required to meet successfully the associated measure for this objective would take approximately 6 hours, which is identical to our estimate for the Stage 1 and Stage 2 requirements. This burden estimate assumes that covered entities are already conducting and reviewing these risk analyses under current HIPAA regulations. Therefore, we have not accounted for the additional burden associated with the conduct or review of such analyses.

Table 6 lists those objectives and associated measures for EPs and eligible hospitals and CAHs. We estimate the objectives and associated measures would take an EP 6 hours 52 minutes to complete, and would take an eligible hospital or CAH 6 hours 52 minutes to complete.

In this proposed rule EPs, eligible hospitals, and CAHs have virtually identical burdens. Eligible hospitals and CAHs are required to report to one additional registry than EPs are required to report. Consequently, we have not prepared lowest and highest burdens. Rather, we have computed a burden for EPs and a burden for eligible hospitals and CAHs.

TABLE 6—BURDEN ESTIMATES

Objectives—Eligible professionals	Objectives—Eligible hospitals/CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative and physical safeguards.	Protect electronic protected health information (ePHI) created or maintained by the CEHRT through the implementation of appropriate technical, administrative and physical safeguards.	Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of data stored in CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider’s risk management process.	6 hours	6 hours.
Generate and transmit permissible prescriptions electronically (eRx).	Generate and transmit permissible discharge prescriptions electronically (eRx).	1. EP Measure: More than 80% of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using CEHRT.	10 minutes	10 minutes.

TABLE 6—BURDEN ESTIMATES—Continued

Objectives—Eligible professionals	Objectives—Eligible hospitals/CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.	Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.	2. Eligible Hospital Measure: More than 25% of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using CEHRT. Measure 1: The EP, eligible hospital and CAH must implement five clinical decision support interventions related to four or more CQMs at a relevant point in patient care for the entire EHR reporting period. Absent four CQMs related to an EP, eligible hospital, or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions.	1 minute	1 minute.
Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.	Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.	Measure 2: The EP, eligible hospital, or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period. Measure 1: More than 80 percent of medication orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry..	10 minutes	10 minutes.
		Measure 2: More than 60 percent of laboratory orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry Measure 3: More than 60 percent of diagnostic imaging orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.		
The EP provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability.	The eligible hospital or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability.	Measure 1: For more than 80 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23): (1) The patient (or the patient authorized representative) is provided access to view online, download, and transmit his or her health information within 24 hours of its availability to the provider; or (2) The patient (or the patient authorized representative) is provided access to an ONC-certified API that can be used by third-party applications or devices to provide patients (or patient authorized representatives) access to their health information, within 24 hours of its availability to the provider	10 minutes	10 minutes.

TABLE 6—BURDEN ESTIMATES—Continued

Objectives—Eligible professionals	Objectives—Eligible hospitals/CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
<p>Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.</p>	<p>Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care</p>	<p>Measure 2: The EP, eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.</p> <p>Measure 1: During the EHR reporting period, more than 25 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the electronic health record made accessible by the provider. An EP may meet the measure by either—</p> <p>(1) More than 25 percent of all unique patients (or patient-authorized representatives) seen by the EP or discharged from the eligible hospital or CAH during the EHR reporting period view, download or transmit to a third party their health information; or</p> <p>(2) More than 25 percent of all unique patients (or patient-authorized representatives) seen by the EP or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period access their health information through the use of an ONC-certified API that can be used by third-party applications or devices.</p> <p>Measure 2: During the EHR reporting period, for more than 35 percent of all unique patients seen by the EP or discharged from the eligible hospital or CAH during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient.</p> <p>Measure 3: Patient-generated health data or data from a non-clinical setting is incorporated into the certified EHR technology for more than 15 percent of all unique patients seen by the EP or discharged by the eligible hospital or CAH during the EHR reporting period.</p>	<p>10 minutes</p>	<p>10 minutes.</p>
<p>The EP provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of certified EHR technology.</p>	<p>The eligible hospital or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using the functions of certified EHR technology.</p>	<p>Measure 1: For more than 50 percent of transitions of care and referrals, the EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care—(1) creates a summary of care record using CEHRT; and (2) electronically exchanges the summary of care record.</p> <p>Measure 2: For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, eligible hospital or CAH incorporates into the patient's record in their EHR an electronic summary of care document from a source other than the provider's EHR system.</p>	<p>10 minutes</p>	<p>10 minutes.</p>

TABLE 6—BURDEN ESTIMATES—Continued

Objectives—Eligible professionals	Objectives—Eligible hospitals/CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
<p>The EP is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.</p>	<p>Measure 3: For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP, eligible hospital, or CAH performs clinical information reconciliation. The provider would choose at least two of the following three clinical information sets on which to perform reconciliations:</p>	1 minute	1 minute.
	<p><i>Medication.</i> Review of the patient's medication, including the name, dosage, frequency, and route of each medication.</p>		
	<p><i>Medication allergy.</i> Review of the patient's known allergic medications.</p>		
	<p><i>Current Problem list.</i> Review of the patient's current and active diagnoses.</p>		
	<p>Providers must report data on an ongoing basis to established public health registries.</p>		
	<p>Measure 1: Immunization Registry Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).</p>		
	<p>Measure 2: Syndromic Surveillance Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care ambulatory setting for EPs, or an emergency or urgent care department for eligible hospitals and CAHs (POS 23).</p>		
	<p>Measure 3: Case Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.</p>		
	<p>Measure 4: Public Health Registry Reporting: The EP, eligible hospital, or CAH is in active engagement with a public health agency to submit data to public health registries.</p>		
	<p>Measure 5: Clinical Data Registry Reporting: The EP, eligible hospital, or CAH is in active engagement to submit data to a clinical data registry.</p>		
.....	<p>Measure 6: Electronic Reportable Laboratory Result Reporting: The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results</p>			
.....	<p>EP Objective: report to 3 of the following registries: Immunization Syndromic Surveillance Case Reporting Public Health Clinical Data</p>			
.....	<p>EPs may choose to report to more than one public health registry to meet the number of measures required to meet the objective.</p>			
.....	<p>EPs may choose to report to more than one clinical data registry to meet the number of measures required to meet the objective.</p>			

TABLE 6—BURDEN ESTIMATES—Continued

Objectives—Eligible professionals	Objectives—Eligible hospitals/CAHs	Measures	Burden estimate per respondent (EPs)	Burden estimate per respondent (hospitals)
	EH/CAH Objective: report to 4 of the following registries: Immunization Syndromic Surveillance Case Reporting Public Health Clinical Data Electronic Reportable Laboratory Results. Eligible hospitals and CAHs may choose to report to more than one public health registry to meet the number of measures required to meet the objective. Eligible hospitals and CAHs may choose to report to more than one clinical data registry to meet the number of measures required to meet the objective.		
Criteria Burden Time to Attest and Report Clinical Quality Measures.	6 hours 52 minutes.	6 hours 52 minutes.
Total—Criteria Burden	6 hours 52 minutes.	6 hours 52 minutes.

In this proposed rule, we estimate that it would take no longer than 6 hours and 52 minutes for an EP to satisfy each of the applicable objectives and associated measures. The total burden hours for an EP to attest to the criteria previously specified would be 6 hours 52 minutes. We estimate that there could be approximately 609,100 non-hospital-based Medicare and Medicaid EPs in 2017.

We estimate the burden for the approximately 13,635 MA EPs in the MAO burden section. We estimate the total burden associated with these requirements for an EP would be 6 hours 52 minutes. The total estimated annual cost burden for all EPs to attest to EHR technology and meaningful use objectives would be \$385,834,395 (506,400 × 6 hours 52 minutes × \$92.25 (mean hourly rate for physicians based on May 2013 BLS data)).

Similarly, eligible hospitals and CAHs would attest that they have met the core meaningful use objectives and associated measures, and would electronically submit the clinical quality measures. We estimate that it would take no longer, than 6 hours and 52 minutes to attest that during the EHR reporting period, they used the certified EHR technology, specify the EHR technology used and satisfied each of the applicable objectives and associated measures. We estimate that there are about 4,900 eligible hospitals and CAHs (3,397 acute care hospitals, 1,395 CAHs, 97 children’s hospitals, and 11 cancer hospitals) that may attest to the aforementioned criteria in FY 2017. We

estimate the total burden associated with these requirements for an eligible hospital and CAH would be 6 hours 52 minutes. The total estimated annual cost burden for all eligible hospitals and CAHs to attest to EHR technology, meaningful use core set and menu set criteria, and electronically submit the clinical quality measures would be \$2,135,204 (4,908 eligible hospitals and CAHs × \$63.46 (6 hours 52 minutes × \$63.46 (mean hourly rate for lawyers based on May 2013 BLS) data)).

B. ICRs Regarding Qualifying MA Organizations (§ 495.210)

In this proposed rule, we estimate that the burden would be significantly less for qualifying MA organizations attesting to the meaningful use of their MA EPs in Stage 3, because qualifying MA EPs use the EHR technology in place at a given location or system, so if certified EHR technology is in place and the qualifying MA organization requires its qualifying MA EPs to use the technology, qualifying MA organizations would be able to determine at a faster rate than individual FFS EPs, that its qualifying MA EPs meaningfully used certified EHR technology. In other words, qualifying MA organizations can make the determination together if the certified EHR technology is required to be used at its facilities, whereas under FFS, each EP likely must make the determination on an individual basis. We estimate that, on average, it would take an individual 45 minutes to collect information necessary to determine if a

given qualifying MA EP has met the meaningful use objectives and measures, and 15 minutes for an individual to make the attestation for each MA EP. Furthermore, the individuals performing the assessment and attesting would not likely be eligible professional, but non-clinical staff. We believe that the individual gathering the information could be equivalent to a GS 11, step 1 (2015 unadjusted for locality rate), with an hourly rate of approximately \$25.00/hour, and the person attesting (and who may bind the qualifying MA organization based on the attestation) could be equivalent to a GS 15, step 1 (2015 unadjusted for locality rate), or approximately \$50.00/hour. Therefore, for the estimated 13,635 potentially qualifying MA EPs, we believe it would cost the participating qualifying MA organizations approximately \$426,050 annually to make the attestations ([10,226 hours × \$25.00] + [3,408 hours × \$50.00]).

C. ICR Regarding State Reporting Requirements (§ 495.316 and § 495.352)

We are proposing to revise 42 CFR 495 regarding state reporting requirements to CMS. With respect to the annual reporting requirements in § 495.316 and the quarterly reporting requirements in § 495.352, we do not believe that the proposed amendments to these reporting requirements would increase the burden on states beyond what was previously finalized under OMB control number 0938–1158 following the Stage 2 final rule. The

deadlines we propose or are considering would be consistent with our past practice, and the changes we propose or consider to the data elements to be reported on would be either reduced or similar in burden. Similarly, we do not expect the proposed amendments regarding the 90-day EHR reporting period for first time meaningful users would impose a burden on states because those amendments would generally maintain the current policy.

However, we are proposing to revise § 495.316 to include a new quarterly reporting requirement. Under the

proposed amendment, states would report quarterly to CMS regarding the EPs and Medicaid eligible hospitals that have successfully demonstrated meaningful use for each payment year. We need this information to ensure that those EPs who are meaningful EHR users in the Medicaid EHR Incentive Program are appropriately exempted from the Medicare payment adjustment. We cannot accurately exempt these providers using the current data received from states. We expect that it would take a state 20 hours each year to submit this report on a quarterly

basis. We believe that the state employee reporting the information could be equivalent to a GS 12, step 1 (2015 unadjusted for locality rate), with an hourly rate of approximately \$30.00/hour. This amount is then reduced by the 90 percent federal contribution for administrative services for Medicaid under the EHR Incentive Programs, this equates to approximately \$3.00/hour. Therefore, for all state Medicaid agencies to report four times per year at 20 hours per report the estimated cost is \$13,460 (4560 hours × \$3.00/hour).

TABLE 7—ESTIMATED ANNUAL INFORMATION COLLECTION BURDEN

Reg section	OMB Control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total cost (\$)
§ 495.x—Objectives/ Measures (EPs)	0938–1158	609,100	609,100	6.86	4,178,426	92.25	385,834,395
§ 495.6—Objectives/ Measures (hospitals/ CAHs)	0938–1158	4,900	4,900	6.86	33,614	63.46	2,135,204
§ 495.210—Gather information for attestation (MA EPs)	0938–1158	13,635	13,635	0.75	10,226	25.00	255,650
§ 495.210—Attestation on behalf of MA EPs	0938–1158	13,635	13,635	0.25	3408.75	50.00	170,400
§ 495.316—Quarterly Reporting	0938–1158	56	224	20	4480	3.00	13,440
Totals		627,635	627,635		4,225,674		388,408,189

Notes:

All non-whole numbers in this table are rounded to 2 decimal places.

There are no capital/maintenance costs associated with the information collection requirements contained in this rule. Therefore, we have removed the associated column from Table 7.

If you would like to comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this final rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS–3310–P], Fax: (202) 395–6974; or Email: *OIRA_submission@omb.eop.gov*.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

This proposed rule would implement the provisions of the ARRA that provide incentive payments to EPs, eligible hospitals, and CAHs participating in Medicare and Medicaid programs that adopt and meaningfully use certified EHR technology. This proposed rule specifies applicable criteria for demonstrating Stage 3 of meaningful use.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism

(August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This proposed rule is anticipated to have an annual effect on the economy of \$100 million or more, making it an economically significant rule under the Executive Order and a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis (RIA) that presents the estimated costs and benefits of this proposed rule.

As noted in section I.A.2. of this proposed rule, this proposed rule is one of two coordinated rules related to the

meaningful use of certified EHR technology. The other is ONC's 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications proposed elsewhere in this issue of the **Federal Register**. This analysis focuses on the impact associated with Stage 3 requirements for meaningful use, the changes in quality measures that would take effect beginning in 2017, and other changes being proposed for the Medicare and Medicaid EHR Incentive Programs.

As we discussed in the Stage 2 final rule (77 FR 54163 through 54291), a number of factors would affect the adoption of EHR systems and demonstration of meaningful use. In this proposed rule, we continue to believe that a number of factors would affect the adoption of EHR systems and demonstration of meaningful use. Readers should understand that these forecasts are also subject to substantial uncertainty since demonstration of meaningful use will depend not only on the standards and requirements for 2017 and for eligible hospitals and EPs, but on future rulemakings issued by the HHS.

We further stated in the 2012 Stage 2 final rule (77 FR 54135 through 54136), the statute provides Medicare and Medicaid incentive payments for the meaningful use of certified EHR technology. Additionally, the Medicaid program also provides incentives for the adoption, implementation, and upgrade of certified EHR technology. Beginning in 2015, payment adjustments are incorporated into the Medicare EHR Incentive Program for providers unable to demonstrate meaningful use. The absolute and relative strength of these is unclear. For example, a provider with relatively small Medicare billings will be less disadvantaged by payment adjustments than one with relatively large Medicare billings. Another uncertainty arises because there are likely to be "bandwagon" effects as the number of providers using EHRs rises, thereby inducing more participation in the incentives program, as well as greater adoption by entities (for example, clinical laboratories) that are not eligible for incentives or subject to payment adjustments, but do business with EHR adopters. It is impossible to predict exactly if and when such effects may take hold.

An uncertainty arises because under current law, physicians are scheduled for a large payment reduction in April 2015 under the sustainable growth rate (SGR) formula, which determines

Medicare physician payment updates. A large payment reduction could cause major changes in physician behavior, enrollee care, and other Medicare provider payments, but the specific nature of these changes is uncertain. Under current law, the remaining EHR incentives for Medicaid or the Medicaid payment adjustments will exert only a minor influence on physician behavior relative to this large physician payment reduction. However, the Congress has legislatively avoided a large physician payment reduction for each year since 2002.

All of these factors taken together make it impossible in this proposed rule to predict with precision the timing or rates of adoption and meaningful use. However, new data is currently available regarding rates of adoption or costs of implementation since the publication of our Stage 1 and Stage 2 final rules. We have included the new data in our estimates, although even these forecasts are still fairly uncertain.

Overall, in this proposed rule, we expect spending under the EHR incentive program for transfer payments to Medicare and Medicaid providers between 2017 and 2020 to be \$3.7 billion (this estimate includes net payment adjustments for Medicare providers who do not achieve meaningful use in the amount of \$0.8 billion). We have also estimated "per entity" costs for EPs, eligible hospitals, and CAHs for implementation/maintenance and reporting requirement costs, not all costs. We believe many adopting entities may achieve dollar savings at least equal to their total costs, and that there may be additional benefits to society. We also believe that implementation costs are significant for each participating entity because providers who were like to qualify as meaningful users of EHRs were likely to purchase certified EHR technology. However, we believe that providers who have already purchased certified EHR technology and participated in Stage 1 or Stage 2 of meaningful use will experience significantly lower costs for participation in the program. We continue to believe that the short-term costs to demonstrate meaningful use of certified EHR technology may be outweighed by the long-term benefits, including practice efficiencies and improvements in medical outcomes. Although both cost and benefit estimates are highly uncertain, the RIA that we have prepared presents the estimated costs and benefits of this proposed rule.

C. Anticipated Effects

The objective of the remainder of this proposed RIA is to summarize the costs and benefits of the HITECH Act incentive program for the Medicare FFS, Medicaid, and MA programs. We also provide assumptions and a narrative addressing the potential costs to the health care industry for implementation of this technology.

1. Overall Effects

a. EHR Technology Development and Certification Costs

We note that the costs incurred by IT developers for EHR technology development and certification to the 2015 Edition certification criteria for health IT are also in part attributable to the requirements for the use of CEHRT established in this proposed rule for Stage 3 of the EHR Incentive Programs. Therefore, to the extent that providers' implementation and adoption costs are attributable to this proposed rule, health IT developers' preparation and development costs would also be attributable as these categories of activities may be directly or indirectly incentivized by the requirements to demonstrate meaningful use. However, even if this Stage 3 proposed rule were not finalized, other CMS programs (for example PQRS and IQR) do require or promote certification to ONC's criteria—or a professional organization or other such entity could require or promote certification to ONC's criteria.¹³ As noted previously, this analysis focuses on the impact associated with Stage 3 requirements for meaningful use for providers; while the development and certification costs are addressed in the the 2015 Edition proposed rule published elsewhere in this issues of the **Federal Register**.

b. Regulatory Flexibility Analysis and Small Entities

The Regulatory Flexibility Act (RFA) requires agencies to prepare an Initial Regulatory Flexibility Analysis to describe and analyze the impact of the proposed rule on small entities unless the Secretary can certify that the regulation will not have a significant impact on a substantial number of small entities. In the health care sector, Small Business Administration (SBA) size standards define a small entity as one with between \$7 million and \$34 million in annual revenues. For the purposes of the RFA, essentially all non-profit organizations are considered small entities, regardless of size.

¹³In this case, the provider implementation and adoption costs discussed in this CMS RIA would instead be attributable to ONC's rulemaking.

Individuals and states are not included in the definition of a small entity. Since the vast majority of Medicare providers (well over 90 percent) are small entities within the RFA's definitions, it is the normal practice of HHS simply to assume that all affected providers are "small" under the RFA. In this case, most EPs, eligible hospitals, and CAHs are either nonprofit or meet the SBA's size standard for small business. We also believe that the effects of the incentives program on many and probably most of these affected entities would be economically significant. Accordingly, this RIA section, in conjunction with the remainder of the preamble, constitutes the required Initial Regulatory Flexibility Analysis (IRFA). We believe that the adoption and meaningful use of EHRs will have an impact on virtually every EP and eligible hospital, as well as CAHs and some EPs and hospitals affiliated with MA organizations. While the program is voluntary, in the first 5 years it carries substantial positive incentives that make it attractive to virtually all eligible entities. Furthermore, entities that do not demonstrate meaningful use of EHR technology for an applicable reporting period will be subject to significant Medicare payment reductions beginning in 2015. These Medicare payment adjustments are expected to motivate EPs, eligible hospitals, and CAHs to adopt and meaningfully use certified EHR technology.

For some EPs, CAHs, and eligible hospitals the EHR technology currently implemented could be upgraded to meet the criteria for certified EHR technology as defined for this program. These costs may be minimal, involving no more than a software upgrade. "Home-grown" EHR systems that might exist may also require an upgrade to meet the certification requirements. We believe many currently used non-certified EHR systems will require significant changes to achieve certification and that EPs, CAHs, and eligible hospitals will have to make process changes to achieve meaningful use.

Data available suggests that more providers have adopted EHR technology since the publication of the Stage 1 final rule. An ONC data brief (No. 16, May 2014) noted that hospital adoption of EHR systems has increased 5 fold since 2008. Nine in ten acute care hospitals possessed CEHRT in 2013, increasing 29 percent since 2011. In January 2014, a Centers for Disease Control and Prevention (CDC) data brief entitled, "Use and Characteristics of Electronic Health Record Systems Among Office-based Physician Practices: United States, 2001 through 2013 found that 78

percent of office-based used any type of EHR systems, up from 18 percent in 2001. The majority of EPs have already purchased certified EHR technology, implemented this new technology, and trained their staff on its use. The costs for implementation and complying with the criteria of meaningful use could lead to higher operational expenses. However, we believe that the combination of payment incentives and long-term overall gains in efficiency may compensate for some of the initial expenditures.

(1) Small Entities

We estimate that EPs would spend approximately \$54,000 to purchase and implement a certified EHR and \$10,000 annually for ongoing maintenance according to the Congressional Budget Office (CBO) (75 FR 44546).

In the paper, Evidence on the Costs and Benefits of Health Information Technology, May 2008, in attempting to estimate the total cost of implementing health IT systems in office-based medical practices, recognized the complicating factors of EHR types, available features and differences in characteristics of the practices that are adopting them. The CBO estimated a cost range of \$25,000 to \$45,000 per physician. Annual operating and maintenance amount was estimated at 12 to 20 percent of initial costs (that is, \$3,000 to \$9,000) per physician. For all eligible hospitals, the range is from \$1 million to \$100 million. Though reports vary widely, we anticipate that the average will be \$5 million for eligible hospitals to achieve meaningful use. We estimate \$1 million for maintenance, upgrades, and training each year per eligible hospital. However, as stated earlier many providers have already purchased systems with expenditures focused on maintenance and upgrades. We believe that future retrospective studies on the costs to implement and EHR and the return on investment (ROI) will demonstrate the actual costs incurred by providers participating in the EHR Incentive Programs.

(2) Conclusion

As discussed later in this analysis, we believe that there are many positive effects of adopting EHR on health care providers. We believe that the net effect on some individual providers may be positive. Accordingly, we believe that the object of the RFA to minimize burden on small entities is met by this proposed rule.

b. Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis

(RIA) if a rule will have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This proposed rule would affect the operations of a substantial number of small rural hospitals because they may be subject to adjusted Medicare payments in 2015 if they fail to adopt certified EHR technology by the applicable reporting period. As stated previously, we have determined that this proposed rule would create a significant impact on a substantial number of small entities, and have prepared a Regulatory Flexibility Analysis as required by the RFA and, for small rural hospitals, section 1102(b) of the Act. Furthermore, any impacts that would arise from the implementation of certified EHR technology in a rural eligible hospital would be positive, with respect to the streamlining of care and the ease of sharing information with other EPs to avoid delays, duplication, or errors. However, the Secretary retains the discretionary statutory authority to make case-by-case exceptions for significant hardships, and has already established certain categories where case-by-case applications may be made such as barriers to internet connectivity that impact health information exchange.

c. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates will require spending in any 1 year \$100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately \$141 million. UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those "federal mandate" costs resulting from—(1) imposing enforceable duties on state, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, state, local, or tribal governments under entitlement programs.

This proposed rule imposes no substantial mandates on states. This program is voluntary for states and states offer the incentives at their option. The state role in the incentive program is essentially to administer the Medicaid incentive program. While this entails certain procedural responsibilities, these do not involve

substantial state expense. In general, each state Medicaid Agency that participates in the incentive program would be required to invest in systems and technology to comply. States would have to identify and educate providers, evaluate their attestations and pay the incentive. However, the federal government would fund 90 percent of the state's related administrative costs, providing controls on the total state outlay.

The investments needed to meet the meaningful use standards and obtain incentive funding are voluntary, and hence not "mandates" within the meaning of the statute. However, the potential reductions in Medicare reimbursement beginning with FY 2015 would have a negative impact on providers that fail to meaningfully use certified EHR technology for the applicable reporting period. We note that we have no discretion as to the amount of those potential payment reductions. Private sector EPs that voluntarily choose not to participate in the program may anticipate potential costs in the aggregate that may exceed \$141 million. However, because EPs may choose for various reasons not to participate in the program, we do not have firm data for the percentage of participation within the private sector. This RIA, taken together with the remainder of the preamble, constitutes the analysis required by UMRA.

d. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This proposed rule will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have a federalism implication. Importantly, state Medicaid agencies are receiving 100 percent match from the federal government for incentives paid and a 90-percent match for expenses associated with administering the program. As previously stated, we believe that state administrative costs are minimal. We note that this proposed rule does add a new business requirement for states, because of the existing systems that would need to be modified to track and report on the new meaningful use requirements for provider attestations. We are providing 90-percent FFP to states for modifying their existing EHR Incentive Program systems. We believe the federal share of the 90-percent match will protect the states from

burdensome financial outlays and as noted previously, states offer the Medicaid EHR incentive program at their option.

2. Effects on EPs, Eligible Hospitals, and CAHs

a. Background and Assumptions

The principal costs of this proposed rule are the additional expenditures that will be undertaken by eligible entities in order to obtain the Medicare and Medicaid incentive payments to adopt, implement or upgrade and/or demonstrate meaningful use of certified EHR technology, and to avoid the Medicare payment adjustments that will ensue if they fail to do so. The estimates for the provisions affecting Medicare and Medicaid EPs, eligible hospitals, and CAHs are somewhat uncertain for several reasons: (1) The program is voluntary although payment adjustments will be imposed on Medicare providers beginning in 2015 if they are unable to demonstrate meaningful use for the applicable reporting period; (2) the criteria for the demonstration of meaningful use of certified EHR technology has been finalized for Stage 1 and Stage 2 and is being proposed for Stage 3, but may change over time; and (3) the impact of the financial incentives and payment adjustments on the rate of adoption of certified EHR technology by EPs, eligible hospitals, and CAHs is difficult to predict based on the information we have currently collected. The net costs and savings shown for this program represent a possible scenario and actual impacts could differ substantially.

Based on input from a number of internal and external sources, we estimated the numbers of EPs and eligible hospitals, including CAHs under Medicare, Medicaid, and MA and used them throughout the analysis.

- About 675,500 Medicare FFS EPs in 2017 (some of whom will also be Medicaid EPs).

- About 60,600 non-Medicare eligible EPs (such as dentists, pediatricians, and eligible non-physicians such as certified nurse-midwives, nurse practitioners, and physicians assistants) could be eligible to receive the Medicaid incentive payments in 2017.

- 4,900 eligible hospitals comprising the following:

- ++ 3,397 acute care hospitals

- ++ 1,395 CAHs

- ++ 97 children's hospitals (Medicaid only)

- ++ 11 cancer hospitals (Medicaid only)

- All eligible hospitals, except for children's and cancer hospitals, may

qualify and apply for both Medicare and Medicaid incentive payments.

- About 16 MA organizations

b. Industry Costs and Adoption Rates

In the Stage 2 final rule (77 FR 54136 through 54146), we estimated the impact on health care providers using information from four studies. In the absence of any more recent estimates that we are aware of, in this proposed rule, we continue to use the same estimates cited in the Stage 2 final rule. We continue to believe that these estimates are reasonably reflective of EHR costs. However, we note, we are unable to delineate all costs due to the great variability in characteristics among the entities that are affected by the proposed rule; the variability includes, but is not limited to, the size of the practice, extent of use of electronic systems, type of system used, number of staff using the EHR system and the cost for maintaining and/or upgrading systems. Based on these studies and current average costs for available certified EHR technology products, we continue to estimate for EPs that the average adopt/implement/upgrade cost is \$54,000 per physician FTE, while annual maintenance costs average \$10,000 per physician FTE.

For all eligible hospitals, we continue to estimate the range is from \$1 million to \$100 million. Although reports vary widely, we continue to anticipate that the average will be \$5 million to achieve meaningful use, because providers who will like to qualify as meaningful users of EHRs will need to purchase certified EHRs. We further acknowledge "certified EHRs" may differ in many important respects from the EHRs currently in use and may differ in the functionalities they contain. We continue to estimate \$1 million for maintenance, upgrades, and training each year. Both of these estimates are based on average figures provided in the 2008 CBO report. However, as noted previously, we are unable to delineate all costs due to the great variability in characteristics among the entities that are affected by the proposed rule; the variability includes, but is not limited to, the size of the hospital, extent of use of electronic systems, type of system used, number of staff using the EHR system and the cost for maintaining and/or upgrading systems.

Industry costs are important, in part, because EHR adoption rates will be a function of these industry costs and the extent to which the costs of "certified EHRs" are higher than the total value of EHR incentive payments available to EPs and eligible hospitals (as well as adjustments, in the case of the Medicare

EHR incentive program) and any perceived benefits including societal benefits. Because of the uncertainties surrounding industry cost estimates, we have made various assumptions about adoption rates in the following analysis in order to estimate the budgetary impact on the Medicare and Medicaid programs.

c. Costs of EHR Adoption for EPs

Since the publication of the Stage 1 final rule, there has been little data published regarding the cost of EHR adoption and implementation. A 2011 study (<http://content.healthaffairs.org/content/30/3/481.abstract>) estimated costs of implementation for a five-physician practice to be \$162,000, with \$85,500 in maintenance expenses in the first year. In the absence of additional data regarding the cost of adoption and implementation costs for certified EHR technology, we proposed to continue to estimate for EPs that the average adopt/implement/upgrade cost is \$54,000 per physician FTE, while annual maintenance costs average \$10,000 per physician FTE, based on the cost estimate of the Stage 1 final rule. However, as noted previously, we are unable to delineate all costs due to the great variability that are affected by but not limited to the size of the practice,

extent of use of electronic systems, type of system used, number of staff using the EHR system, and the cost for maintaining and/or upgrading systems.

d. Costs of EHR Adoption for Eligible Hospitals

According to the American Hospital Association 2008 Survey, the range in yearly information technology spending among hospitals ranged from \$36,000 to over \$32 million. EHR system costs specifically were reported by other experts to run as high as \$20 million to \$100 million (77 FR 54139). We note that recently we have seen about 96 percent of eligible hospitals have received at least one incentive payment under either the Medicare or Medicaid programs. However, as noted previously, we are unable to delineate all costs due to the great variability that are affected by but not limited to the size of the eligible hospital, extent of use of electronic systems, type of system used, number of staff using the EHR system, and the cost for maintaining and/or upgrading systems.

3. Medicare Incentive Program Costs

The estimates for the HITECH Act provisions are based on the economic assumptions underlying the President's FY 2016 Budget. Under the statute, Medicare incentive payments for

certified EHR technology are excluded from the determination of MA capitation benchmarks. We continue to expect a negligible impact on benefit payments to hospitals and EPs from Medicare and Medicaid because of the implementation of EHR technology.

As noted at the beginning of this analysis, it is difficult to predict the actual impacts of the HITECH Act with great certainty. We believe the assumptions and methods described herein are reasonable for estimating the financial impact of the provisions on the Medicare and Medicaid programs, but acknowledge the wide range of possible outcomes.

a. Medicare Eligible Professionals (EPs)

We began making EHR Incentive payments in 2011. Medicare payments are to be paid for the successful demonstration on meaningful use through CY 2016. Due to the payment lag, some payments may be issued in CY 2017. To avoid the Medicare payment adjustment beginning in 2015, EPs need to successfully demonstrate meaningful use regardless of whether they earn an incentive payment. We estimated the percentage of the remaining EPs who would be meaningful users each calendar year. Table 8 shows the results of these calculations.

TABLE 8—MEDICARE EPS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY

	Calendar year			
	2017	2018	2019	2020
Medicare EPs who have claims with Medicare (thousands)	675.5	683.3	691.1	698.8
Non-Hospital-based Medicare EPs (thousands)	609.1	616.1	623.1	630.1
Percent of EPs who are Meaningful Users	70	73	75	78
Meaningful Users (thousands)	426.4	446.7	467.3	488.3

Our estimates of the incentive payment costs and payment adjustment savings are presented in Table 9. They reflect actual historical data and our assumptions about the proportion of EPs who will demonstrate meaningful use of certified EHR technology. Estimated

costs are expected to decrease in 2017 through 2020 due to a smaller number of new EPs that would achieve meaningful use and the cessation of the incentive payment program. Payment adjustment receipts represent the estimated amount of money collected

due to the payment adjustments for those not achieving meaningful use. Estimated net costs for the Medicare EP portion of the HITECH Act are also shown in Table 9.

TABLE 9—ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE EPS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY

[In Billions]

Fiscal Year	Incentive payments	Payment adjustment receipts	Benefit payments	Net total
2017	\$0.6	–\$0.2	—	\$0.3
2018	—	–0.2	—	–0.2
2019	—	–0.2	—	–0.2
2020	—	–0.1	—	–0.1

b. Medicare Eligible Hospitals and CAHs

In brief, the estimates of hospital adoption were developed by calculating projected incentive payments and then making assumptions about how rapidly hospitals would adopt meaningful use.

Specifically, the first step in preparing estimates of Medicare program costs for eligible hospitals was to determine how many eligible hospitals already received payments under the EHR Incentive program and for what years those payments were received. In order to do this, we used the most recent available data that listed the recipients of incentive payments, and the year and payment amount. This information pertained to eligible hospitals receiving payments through September 2014.

We assume that all eligible hospitals that receive a payment in the first year will receive payments in future years. We also assume the eligible hospitals that have not yet received any incentive payments will eventually achieve meaningful use (either to receive incentive payments or to avoid payment adjustments). We assume that all

eligible hospitals would achieve meaningful use by 2018. No new incentive payments would be paid after 2016. However, some incentive payments originating in 2016 would be paid in 2017.

The average incentive payment for each eligible hospital was \$1.5 million in the first year. In later years, the amount of the incentive payments drops according to the schedule allowed in law. The average incentive payment for CAHs received in the first year was about \$950,000. The average incentive payment received in the second year was about \$332,500. The average incentive payment received in the third year was about \$475,000. These average amounts were used for these incentive payments in the future. The third year average was also used for the fourth year. These assumptions about the number of hospitals achieving meaningful use in a particular year and the average amount of an incentive payment allows us to calculate the total amount of incentive payments to be made and the amount of payment adjustments for those hospitals who have not achieved meaningful use. The

payment incentives available to hospitals under the Medicare and Medicaid EHR Incentive Programs are included in our regulations at 42 CFR part 495. We further estimate that there are 16 MA organizations that might be eligible to participate in the incentive program. Those plans have 32 eligible hospitals. The costs for the MA program have been included in the overall Medicare estimates.

The estimated payments to eligible hospitals were calculated based on the hospitals' qualifying status and individual incentive amounts under the statutory formula. Similarly, the estimated payment adjustments for non-qualifying hospitals were based on the market basket reductions and Medicare revenues. The estimated savings in Medicare eligible hospital benefit expenditures resulting from the use of hospital certified EHR systems were discussed earlier in this section. We assumed no future growth in the total number of hospitals in the U.S. because growth in acute care hospitals has been minimal in recent years. The results are shown in Table 10.

TABLE 10—ESTIMATED COSTS (+) AND SAVINGS (–) FOR MEDICARE ELIGIBLE HOSPITALS DEMONSTRATING MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY

[In billions]

Fiscal year	Incentive payments	Payment adjustment receipts	Benefit payments	Net total
2017	\$1.6	(¹)	(¹)	\$1.6
2018	0.0	(¹)	(¹)	(¹)
2019	0.0	0.0	(¹)	(¹)
2020	0.0	0.0	(¹)	(¹)

¹ Savings of less than \$50 million. All numbers are projections.

4. Medicaid Incentive Program Costs

Under section, 4201 of the HITECH Act, states and territories can voluntarily participate in the Medicaid EHR Incentive Program. However, as of the writing of this proposed rule, all

states already participate. The payment incentives available to EPs and eligible hospitals under the Medicaid EHR Incentive Program are included in our regulations at 42 CFR part 495. The federal costs for Medicaid incentive payments to providers who can

demonstrate meaningful use of EHR technology were estimated similarly to the estimates for Medicare eligible hospitals and EPs. Table 11 shows our estimates for the net Medicaid costs for eligible hospitals and EPs.

TABLE 11—ESTIMATED FEDERAL COSTS (+) AND SAVINGS (–) UNDER MEDICAID

[In \$billions]

Fiscal year	Incentive payments		Benefit payments	Net total
	Hospitals	Eligible professionals		
2017	0.4	0.8	(¹)	1.2
2018	0.1	0.5	(¹)	0.6
2019	0	0.3	(¹)	0.3
2020	0.0	0.2	(¹)	0.2

¹ Savings of less than \$50 million.

a. Medicaid EPs

TABLE 12—ASSUMED NUMBER OF NONHOSPITAL BASED MEDICAID EPS WHO WOULD BE MEANINGFUL USERS OF CERTIFIED EHR TECHNOLOGY
[Population figures in thousands]

		Calendar year			
		2017	2018	2019	2020
A	EPs who meet the Medicaid patient volume threshold	101.3	102.3	103.3	104.4
B	Medicaid only Eps	60.6	61.7	62.9	64.0
	Total Medicaid EPs (A + B)	161.8	164.0	166.2	168.4
	Percent of EPs receiving incentive payment during year	44.7%	30.9%	20.7%	14.3%
	Number of EPs receiving incentive payment during year	72.4	50.7	34.5	24.0
	Percent of EPs who have ever received incentive payment	67.9%	74.7%	78.0%	81.1%
	Number of EPs who have ever received incentive payment	109.9	122.5	129.6	136.6

It should be noted that since the Medicaid EHR Incentive Program provides that a Medicaid EP can receive an incentive payment in his or her first year because he or she has demonstrated a meaningful use or because he or she has adopted, implemented, or upgraded certified EHR technology, these participation rates include not only meaningful users but eligible providers implementing certified EHR technology as well.

b. Medicaid Hospitals

Medicaid incentive payments to most eligible hospitals were estimated using the same methodology as described previously for Medicare eligible hospitals and shown in Table 10. Many eligible hospitals may qualify to receive both the Medicare and Medicaid incentive payment. We assume that all eligible hospitals would achieve meaningful use by 2016. However, many of these eligible hospitals would have already received the maximum amount of incentive payments. Table 13 shows our assumptions about the remaining incentive payments to be paid.

TABLE 13—ESTIMATED PERCENTAGE OF HOSPITALS THAT COULD BE PAID FOR MEANINGFUL USE AND ESTIMATED PERCENTAGE PAYABLE IN YEAR

Fiscal year	Percent of hospitals who are meaningful users	Percent of hospitals being paid
2017	100.0	13.5
2018	100.0	5.2
2019	100.0	1.5
2020	100.0	0.0

As stated previously, the estimated eligible hospital incentive payments were calculated based on the eligible hospitals' qualifying status and individual incentive amounts payable under the statutory formula. The

average Medicaid incentive payment in the first year was \$1 million. The estimated savings in Medicaid benefit expenditures resulting from the use of certified EHR technology are discussed in section V.C.4. of this proposed rule. Since we use Medicare data and little data existed for children's hospitals, we estimated the Medicaid incentives payable to children's hospitals as an add-on to the base estimate, using data on the number of children's hospitals compared to non-children's hospitals.

5. Benefits for all EPs and all Eligible Hospitals

In this proposed rule, we have not quantified the overall benefits to the industry, nor to eligible hospitals or EPs in the Medicare, Medicaid, or MA programs. Although information on the costs and benefits of adopting systems that specifically meet the requirements for the EHR Incentive Programs (for example, certified EHR technology) has not yet been collected, and although some studies question the benefits of health information technology, a 2011 study completed by ONC (Buntin et al. 2011 "The Benefits of Health Information Technology: A Review of the Recent Literature Shows Predominantly Positive Results" Health Affairs.) found that 92 percent of articles published from July 2007 up to February 2010 reached conclusions that showed the overall positive effects of health information technology on key aspects of care, including quality and efficiency of health care. Among the positive results highlighted in these articles were decreases in patient mortality, reductions in staffing needs, correlation of clinical decision support to reduced transfusion and costs, reduction in complications for patients in hospitals with more advanced health IT, and a reduction in costs for hospitals with less advanced health IT. A subsequent 2013 study completed by the RAND Corporation for ONC (Shekelle et al. 2013 "Health

Information Technology: An Updated Systemic Review with a Focus on Meaningful Use Functionalities") found 77 percent of articles published between January 2010 to August 2013 that evaluated the effects of health IT on healthcare quality, safety, and efficiency reported findings that were at least partially positive. The Centers for Disease Control and Prevention publication in January 2014, (Hsiao et al, "Use and Characteristics of Electronic Health Record Systems Among Office-based Physician Practices: United states, 2001–2013") concluded that the adoption of basic EHR systems by office-based physicians increased 21 percent between 2012 and 2013, varying widely across the states ranging from 21 percent in New Jersey to 83 percent in North Dakota. Another study, at one hospital emergency room in Delaware, showed the ability to download and create a file with a patient's medical history saved the ER \$545 per use, mostly in reduced waiting times. A pilot study of ambulatory practices found a positive ROI within 16 months and annual savings thereafter (Greiger et al. 2007, A Pilot Study to Document the Return on Investment for Implementing an Ambulatory Electronic Health Record at an Academic Medical Center <http://www.journalacs.org/article/S1072-7515%2807%2900390-0/abstract-article-footnote-1>.) Another study compared the productivity of 75 providers within a large urban primary care practice over a 4-year period showed increases in productivity of 1.7 percent per month per provider after EHR adoption (DeLeon et al. 2010, "The business end of health information technology"). Some vendors have estimated that EHRs could result in cost savings of between \$100 and \$200 per patient per year. As participation and adoption increases, there will be more opportunities to capture and report on cost savings and benefits.

6. Benefits to Society

According to the CBO study “Evidence on the Costs and Benefits of Health Information Technology” (<http://www.cbo.gov/ftpdocs/91xx/doc9168/05-20-HealthIT.pdf>) when used effectively, EHRs can enable providers to deliver health care more efficiently. For example, the study states that EHRs can reduce the duplication of diagnostic tests, prompt providers to prescribe cost-effective generic medications, remind patients about preventive care, reduce unnecessary office visits, and assist in managing complex care. This is consistent with the findings in the ONC study cited previously. Further, the CBO report claims that there is a potential to gain both internal and external savings from widespread adoption of health IT, noting that internal savings will likely be in the reductions in the cost of providing care, and that external savings could accrue to the health insurance plan or even the patient, such as the ability to exchange information more efficiently. However, it is important to note that the CBO identifies the highest gains accruing to large provider systems and groups and claims that office-based physicians may not realize similar benefits from purchasing health IT products. At this time, there is limited data regarding the efficacy of health IT for smaller practices and groups, and the CBO report notes that this is a

potential area of research and analysis that remains unexamined. The benefits resulting specifically from this proposed rule are even harder to quantify because they represent, in many cases, adding functionality to existing systems and reaping the network externalities created by larger numbers of providers participating in information exchange.

In the Stage 2 final rule at 77 FR 54144, we discussed research documenting the association of EHRs with improved outcomes among diabetics (Hunt, JS et al. (2009) “The impact of a physician-directed health information technology system on diabetes outcomes in primary care: A pre- and post-implementation study” *Informatics in Primary Care* 17(3): 165-74; Pollard, C et al. (2009) “Electronic patient registries improve diabetes care and clinical outcomes in rural community health centers” *Journal of Rural Health* 25(1): 77-84) and trauma patients (Deckelbaum, D. et al. (2009) “Electronic medical records and mortality in trauma patients” *The Journal of Trauma: Injury, Infection, and Critical Care* 67(3): 634-636), enhanced efficiencies in ambulatory care settings (Chen, C et al. (2009) “The Kaiser Permanente Electronic Health Record: Transforming and Streamlining Modalities Of Care. “Health Affairs” 28(2): 323-333), and improved outcomes and lower costs in hospitals

(Amarasingham, R. et al. (2009) “Clinical information technologies and inpatient outcomes: A multiple hospital study” *Archives of Internal Medicine* 169(2): 108-14). The 2013 ONC report cited previously reported findings from their literature review on health IT and safety of care, health IT and quality of care, health IT and safety of care, and health IT and efficiency of care in ambulatory and non-ambulatory care settings. The report indicated that a majority of studies that evaluated the effects of health IT on healthcare quality, safety, and efficiency reported findings that were at least partially positive. The report concluded that their findings “suggested that health IT, particularly those functionalities included in the Meaningful Use . . . , can improve healthcare quality and safety.” However, data relating specifically to the EHR Incentive Programs is limited at this time.

7. Summary

In this proposed rule, the total cost to the Medicare and Medicaid programs between 2017 and 2020 is estimated to be \$3.7 billion in transfers. As discussed in section V.C.4. of this proposed rule, we do not estimate total costs to the provider industry, but rather provide a possible per EP and per eligible hospital outlay for implementation and maintenance.

TABLE 14—ESTIMATED EHR INCENTIVE PAYMENTS AND BENEFITS IMPACTS ON THE MEDICARE AND MEDICAID PROGRAMS OF THE HITECH EHR INCENTIVE PROGRAM (FISCAL YEAR)
[In billions]

Fiscal year	Medicare eligible		Medicaid eligible		Total
	Hospitals	Professionals	Hospitals	Professionals	
2017	\$1.6	\$0.3	\$0.4	\$0.8	\$3.1
2018	0.0	−0.2	0.1	0.5	0.4
2019	0.0	−0.2	0.0	0.3	0.1
2020	0.0	−0.1	0.0	0.2	0.1
Total	1.6	−0.2	0.5	1.8	3.7

D. Alternatives Considered

As stated in the Stage 1 final rule (75 FR 44546), HHS has no discretion to change the incentive payments or payment adjustment reductions specified in the statute for providers that adopt or fail to adopt a certified EHR and demonstrate meaningful use of certified EHR technology. However, we have discretion around how best to meet the HITECH Act requirements for meaningful use for FY 2017 and subsequent years, which we have exercised in this proposed rule. Additionally, we have used our discretion to appropriately propose the

timing of registration, attestation and payment requirements to allow EPs and eligible organizations as much time as possible in coordination with the anticipated certification of EHR technology to obtain and meaningfully use certified EHRs. We recognize that there may be additional costs that result from various discretionary policy choices by providers. However, those costs cannot be estimated and are not captured in this analysis.

E. Accounting Statement and Table

Whenever a rule is considered a significant rule under Executive Order 12866, we are required to develop an

accounting statement indicating the classification of the expenditures associated with the provisions of this proposed rule. Monetary annualized benefits and non-budgetary costs are presented as discounted flows using 3 percent and 7 percent factors in the following Table 15. We are not able to explicitly define the universe of those additional costs, nor specify what the high or low range might be to implement EHR technology in this proposed rule. We note that federal annualized monetized transfers represent the net total of annual incentive payments in the Medicare and Medicaid EHR Incentive programs less

the reductions in Medicare payments to providers failing to demonstrate meaningful use as a result of the related Medicare payment adjustments.

Expected qualitative benefits include improved quality of care, better health outcomes, reduced errors and the like. Private industry costs would include the impact of EHR activities such as

temporary reduced staff productivity related to learning how to use the EHR, the need for additional staff to work with HIT issues, and administrative costs related to reporting.

TABLE 15—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES CYs 2017 THROUGH 2020
[In millions]

CATEGORY				
Qualitative	BENEFITS			
	Expected qualitative benefits include improved quality of care, better health outcomes, reduced errors and the like.			
	COSTS			
	Year dollar	Estimates (in millions)	Unit discount rate	Period covered
.....	Primary Estimate			
Annualized Monetized Costs to Private Industry Associated with Reporting Requirements	2017	\$478.1 \$478.4	7% 3%	CY 2017
Qualitative—Other private industry costs associated with the adoption of EHR technology.	These costs would include the impact of EHR activities such as reduced staff productivity related to learning how to use the EHR technology, the need for additional staff to work with HIT issues, and administrative costs related to reporting.			
Federal Annualized Monetized	TRANSFERS			
	Year dollar	Estimates (in millions)	Unit discount rate	Period covered
	2017	\$1,000.4 \$954.8	7% 3%	CYs 2017–2020
From Whom To Whom?	Federal Government to Medicare- and Medicaid-eligible professionals and hospitals.			

F. Conclusion

The previous analysis, together with the remainder of this preamble, provides an RIA. We believe there are many positive effects of adopting EHR on health care providers. We believe there are benefits that can be obtained by eligible hospitals and EPs, including: Reductions in medical recordkeeping costs, reductions in repeat tests, decreases in length of stay, and reduced errors. Health IT can enable providers to deliver health care more efficiently. For example, EHRs can reduce the duplication of diagnostic tests, prompt providers to prescribe cost-effective generic medications, remind patients about preventive care, reduce unnecessary office visits, and assist in managing complex care. We also believe that internal savings will likely come through the reductions in the cost of providing care. We believe that the net effect on individual providers may be positive over time in many cases.

Accordingly, we believe that the object of the Regulatory Flexibility Analysis to minimize burden on small entities are met by this proposed rule. We invite public comments on the analysis and request any additional data that would help us determine more accurately the impact on the EPs and eligible hospitals affected by the proposed rule.

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this rule.

List of Subjects in 42 CFR Part 495

Administrative practice and procedure, Electronic health records, Health facilities, Health professions, Health maintenance organizations (HMO), Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 495 as set forth below:

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 1. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 495.4 is amended as follows:

- A. Adding the definition for “Application-program interface (API)”.
- B. Revising the definition of “Certified electronic health record technology”.
- C. Amending the definition of “EHR reporting period” by—
 - i. Redesignating paragraphs (1)(i), (1)(ii), (1)(iii) introductory text, (1)(iii)(A), (1)(iii)(B), (1)(iii)(C), (1)(iii)(D), and (1)(iv) as paragraphs (1)(i)(A), (1)(i)(B), (1)(i)(C) introductory text, (1)(i)(C)(1), (1)(i)(C)(2), (1)(i)(C)(3), (1)(1)(C)(4), and (1)(i)(D), respectively.
 - ii. Adding new paragraph (1)(i) introductory text.

- iii. Adding a new paragraph (1)(ii).
- iv. Redesignating paragraphs (2)(i), (2)(ii), (2)(iii) introductory text, (2)(iii)(A), (2)(iii)(B), (2)(iii)(C), and (2)(iii)(D), as paragraphs (2)(i)(A), (2)(i)(B), (2)(i)(C) introductory text and (2)(i)(C)(1), (2)(i)(C)(2), (2)(i)(C)(3), and (2)(i)(C)(4), respectively.
- v. Adding new paragraph (2)(i) introductory text.
- vi. Adding a new paragraph (2)(ii).
- D. Amending the definition of “*EHR reporting period for a payment adjustment year*” by:
 - i. Redesignating paragraphs (1)(i)(A), (1)(i)(B), (1)(ii), (1)(iii)(A), and (1)(iii)(B) as paragraphs (1)(i)(A)(1), (1)(i)(A)(2), (1)(i)(B), (1)(i)(C)(1) and (1)(i)(C)(2), respectively.
 - ii. In newly redesignated paragraph (1)(i)(A)(1), by removing the cross-reference “paragraphs (1)(i)(B), (ii), and (iii)” and adding in its place the cross-reference “paragraphs (1)(i)(A)(2), (1)(i)(B), and (1)(i)(C)”.
 - iii. In newly redesignated paragraph (1)(i)(A)(2), by removing the cross-reference “paragraphs (1)(iii) or (iv)” and adding in its place the cross-reference “paragraph (1)(i)(C)”.
 - iv. Adding new paragraph (1)(i) introductory text.
 - v. Adding a new paragraph (1)(ii).
 - vi. Redesignating paragraphs (2)(i)(A), (2)(i)(B), (2)(ii), (2)(iii)(A), and (2)(iii)(B) as paragraphs (2)(i)(A)(1), (2)(i)(A)(2), (2)(i)(B), (2)(i)(C)(1) and (2)(i)(C)(2), respectively.
 - vii. In newly redesignated paragraph (2)(i)(A)(1), by removing the cross-reference “paragraphs (2)(i)(B), (ii), and (iii)” and adding in its place the cross-reference “paragraphs (2)(i)(A)(2), (2)(i)(B), and (2)(i)(C)”.
 - viii. In newly redesignated paragraph (2)(i)(A)(2), by removing the cross-reference “paragraph (2)(iii)” and adding in its place the cross-reference “paragraph (2)(i)(C)”.
 - ix. Adding new paragraph (2)(i) introductory text.
 - x. Adding new paragraph (2)(ii).
 - xi. Redesignating paragraphs (3)(i) and (3)(ii) as paragraphs (3)(i)(A) and (3)(i)(B).
 - xii. In newly redesignated paragraph (3)(i)(A), by removing the cross-reference “paragraph (3)(ii)” and adding in its place the cross-reference “paragraph (3)(i)(B)”.
 - xiii. Adding new paragraph (3)(i) introductory text.
 - xiv. Adding new paragraph (3)(ii).
- E. In the paragraph (1) of the definition of “*Meaningful EHR User*” by removing the reference “under § 495.6” and adding in its place the reference to “under § 495.6 or 495.7”.

The additions read as follows:

§ 495.4 Definitions.

* * * * *

Application-program interface (API) means a set of programming protocols established for multiple purposes. APIs may be enabled by a provider or provider organization to provide the patient with access to their health information through a third-party application with more flexibility than often found in many current “patient portals.”

Certified electronic health record technology (CEHRT) means the following:

(1) For any Federal fiscal year (FY) or calendar year (CY) before 2018, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that—

- (i) Meets the—
 - (A) 2014 Edition Base EHR definition (as defined at 45 CFR 170.102); or
 - (B) 2015 Edition Base EHR definition (as defined at 45 CFR 170.102); or
 - (ii) Has been certified to the following certification criteria:

- (A)(1) CPOE at—
 - (i) 45 CFR 170.314(a)(1), (18), (19) or (20); or
 - (ii) 45 CFR 170.315(a)(1), (2) or (3);
- (2)(i) Record demographics at 45 CFR 170.314(a)(3); or
- (ii) 45 CFR 170.315(a)(5).
- (3)(i) Problem list at 45 CFR 170.314(a)(5); or
- (ii) 45 CFR 170.315(a)(7).
- (4)(i) Medication list at 45 CFR 170.314(a)(6); or (ii) 45 CFR 170.315(a)(8).
- (5)(i) Medication allergy list 45 CFR 170.314(a)(7); or (ii) 45 CFR 170.315(a)(9);

(6)(i) Clinical decision support at 45 CFR 170.314(a)(8); or (ii) 45 CFR 170.315(a)(10).

(7) Health information exchange at transitions of care at one of the following:

- (i) 45 CFR 170.314(b)(1) and (2).
- (ii) 45 CFR 170.314(b)(1), (b)(2), and (h)(1).
- (iii) 45 CFR 170.314(b)(1), (b)(2), and (b)(8).
- (iv) 45 CFR 170.314(b)(1), (b)(2), (b)(8), and (h)(1).
- (v) 45 CFR 170.314(b)(8) and (h)(1).
- (vi) 45 CFR 170.314(b)(1), (b)(2), and 170.315(h)(2).
- (vii) 45 CFR 170.314(b)(1), (b)(2), (h)(1), and 170.315(h)(2).
- (viii) 45 CFR 170.314(b)(1), (b)(2), (b)(8), and 170.315(h)(2).
- (ix) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), and 170.315(h)(2).
- (x) 45 CFR 170.314(b)(8), (h)(1), and 170.315(h)(2).
- (xi) 45 CFR 170.314(b)(1), (b)(2), and 170.315(b)(1).

(xii) 45 CFR 170.314(b)(1), (b)(2), (h)(1), and 170.315(b)(1).

(xiii) 45 CFR 170.314(b)(1), (b)(2), (b)(8), and 170.315(b)(1).

(xiv) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), and 170.315(b)(1).

(xv) 45 CFR 170.314(b)(8), (h)(1), and 170.315(b)(1).

(xvi) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), 170.315(b)(1), and 170.315(h)(1).

(xvii) 45 CFR 170.314(b)(1), (b)(2), (b)(8), (h)(1), 170.315(b)(1), and 170.315(h)(2).

(xviii) 45 CFR 170.314(h)(1) and 170.315(b)(1).

(xix) 45 CFR 170.315(b)(1) and (h)(1).

(xx) 45 CFR 170.315(b)(1) and (h)(2).

(xxi) 45 CFR 170.315(b)(1), (h)(1), and (h)(2).

(B) Clinical quality measures at 45 CFR 170.314(c)(1) or 170.315(c)(1).

(C) The 2014 Edition or 2015 Edition certification criteria that are necessary to be a Meaningful EHR User (as defined in this section), including the following:

(1) The applicable automated numerator recording and automated measure calculation certification criteria that support attestation as a Meaningful EHR User at 45 CFR 170.315(g)(1) and (2) and 45 CFR 170.314(g)(1) and (2).

(2) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.314(c)(2) and (c)(3) or 45 CFR 170.315(c)(2) and (c)(3).

(2) For 2018 and subsequent years, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102) and has been certified to the 2015 Edition health IT certification criteria that—

- (i)(A) Include the capabilities to record 45 CFR 170.315(a)(14); or
- (B) Create and incorporate family health history 45 CFR 170.315(a)(15).
- (ii) Include the capabilities that support patient health information capture at 45 CFR 170.315(a)(19); and
- (iii) Are necessary to be a Meaningful EHR User (as defined in this section), including the following:

(A) The applicable automated numerator recording and automated measure calculation certification criteria that support attestation as a Meaningful EHR User at 45 CFR 170.315(g)(1) and (2).

(B) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures under the 2015 Edition certification criteria 45 CFR 170.315(c)(2) and (c)(3).

* * * * *

EHR reporting period. * * *

(1) * * *

(i) The following are applicable before CY 2017.

* * * * *

(ii) The following are applicable beginning in CY 2017 under the Medicaid EHR Incentive Program:

(A) For the payment year in which the EP is first demonstrating he or she is a meaningful EHR user, any continuous 90-day period within the calendar year.

(B) For the subsequent payment years following the payment year in which the EP first successfully demonstrates he or she is a meaningful EHR user, the calendar year.

(2) * * *

(i) The following are applicable before CY 2017:

* * * * *

(ii) The following are applicable beginning in CY 2017 under the Medicaid EHR Incentive Program:

(A) For the payment year in which the eligible hospital or CAH is first demonstrating it is a meaningful EHR user, any continuous 90-day period within the calendar year.

(B) For the subsequent payment years following the payment year in which the eligible hospital or CAH first successfully demonstrates it is a meaningful EHR user, the calendar year.

EHR reporting period for a payment adjustment year. * * *

(1) * * *

(i) The following are applicable before CY 2017:

* * * * *

(ii) The following are applicable beginning in CY 2017:

(A) Except as provided under paragraph (1)(ii)(B) of this definition, the calendar year that is 2 years before the payment adjustment year.

(B) If an EP is demonstrating under the Medicaid EHR Incentive Program that he or she is a meaningful EHR user for the first time in the calendar year that is 2 years before the payment adjustment year, then the continuous 90-day period that is the EHR reporting period for the Medicaid incentive payment within such (2 years prior) calendar year.

(2) * * *

(i) The following are applicable before CY 2017:

* * * * *

(ii) The following are applicable beginning in CY 2017:

(A) Except as provided in paragraph (2)(ii)(B) of this definition, the calendar year that is 2 years before the payment adjustment year.

(B) If an eligible hospital is demonstrating under the Medicaid EHR

Incentive Program that it is a meaningful EHR user for the first time in the calendar year that is 2 years before the payment adjustment year, then the continuous 90-day period that is the EHR reporting period for the Medicaid incentive payment within such (2 years prior) calendar year.

(3) * * *

(i) The following are applicable before CY 2017:

* * * * *

(ii) The following are applicable beginning in CY 2017:

(A) Except as provided in paragraph (3)(ii)(B) of this definition, the calendar year that begins on the first day of the second quarter of the Federal fiscal year that is the payment adjustment year.

(B) If a CAH is demonstrating under the Medicaid EHR Incentive Program that it is a meaningful EHR user for the first time in the calendar year that begins on the first day of the second quarter of the Federal fiscal year that is the payment adjustment year, then any continuous 90-day period within such calendar year.

* * * * *

■ 3. Section 495.6 is amended by revising the section heading and adding introductory text to read as follows:

§ 495.6 Meaningful use objectives and measures for EPs, eligible hospitals, and CAHs before 2018.

The following criteria are applicable before 2018:

* * * * *

■ 4. Section 495.7 is added to read as follows:

§ 495.7 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals, and CAHs for 2018 and subsequent years.

The following criteria are optional for EPs, eligible hospitals, and CAHs in 2017 as outlined at § 495.8(a)(2)(i)(E)(3) and (b)(2)(E)(3) and applicable for all EPs, eligible hospitals, and CAHs for 2018 and subsequent years:

(a) *Stage 3 criteria for EPs.*(1) *General rule regarding Stage 3 criteria for meaningful use for EPs.* Except as specified in paragraphs (a)(2) through (a)(3) of this section, EPs must meet all objectives and associated measures of the Stage 3 criteria specified in paragraph (d) of this section to meet the definition of a meaningful EHR user.(2) *Selection of measures for specified objectives in paragraph (d) of this section.* An EP may meet the criteria for 2 out of the 3 measures associated with an objective, rather than meeting the criteria for all 3 of the measures, if the EP meets all of the following requirements:

(i) Must ensure that the objective in paragraph (d) of this section includes an option to meet 2 out of the 3 associated measures.

(ii) Meets the threshold for 2 out of the 3 measures for that objective.

(iii) Attests to all 3 of the measures for that objective

(3) *Exclusion for nonapplicable objectives and measures.*

(i) An EP may exclude a particular objective that includes an option for exclusion contained in paragraph (d) of this section, if the EP meets all of the following requirements:

(A) Meets the criteria in the applicable objective that would permit the exclusion.

(B) Attests to the exclusion.

(ii) An EP may exclude a measure within an objective which allows for a provider to meet the threshold for 2 of the 3 measures, as outlined in paragraph (a)(2) of this section, in the following manner:

(A)(1) Meets the criteria in the applicable measure or measures that would permit the exclusion; and

(2) Attests to the exclusion or exclusions.

(B)(1) Meets the threshold; and

(2) Attests to any remaining measure or measures.

(4) *Exception for Medicaid EPs who adopt, implement or upgrade in their first payment year.* For Medicaid EPs who adopt, implement or upgrade its certified EHR technology in their first payment year, the meaningful use objectives and associated measures of the Stage 3 criteria specified in paragraph (d) of this section, apply beginning with the second payment year, and do not apply to the first payment year.(b) *Stage 3 criteria for eligible hospitals and CAHs.*(1) *General rule regarding Stage 3 criteria for meaningful use for eligible hospitals or CAHs.* Except as specified in paragraphs (b)(2) through (b)(3) of this section, eligible hospitals and CAHs must meet all objectives and associated measures of the Stage 3 criteria specified in paragraph (d) of this section to meet the definition of a meaningful EHR user.(2) *Selection of measures for specified objectives in paragraph (d) of this section.* An eligible hospital or CAH may meet the criteria for 2 out of the 3 measures associated with an objective, rather than meeting the criteria for all 3 of the measures, if the eligible hospital or CAH meets all of the following requirements:

(i) Must ensure that the objective in paragraph (d) of this section includes an option to meet 2 out of the 3 associated measures.

(ii) Meets the threshold for 2 out of the 3 measures for that objective.

(iii) Attests to all 3 of the measures for that objective.

(3) *Exclusion for nonapplicable objectives and measures.*

(i) An eligible hospital or CAH may exclude a particular objective that includes an option for exclusion contained in paragraph (d) of this section, if the eligible hospital or CAH meets all of the following requirements:

(A) Meets the criteria in the applicable objective that would permit the exclusion.

(B) Attests to the exclusion.

(ii) An eligible hospital or CAH may exclude a measure within an objective which allows for a provider to meet the threshold for 2 of the 3 measures, as outlined in paragraph (b)(2) of this section, in the following manner:

(A)(1) Meets the criteria in the applicable measure or measures that would permit the exclusion; and

(2) Attests to the exclusion or exclusions.

(B)(1) Meets the threshold; and

(2) Attests to any remaining measure or measures.

(4) *Exception for Medicaid eligible hospitals or CAHs that adopt, implement or upgrade in their first payment year.* For Medicaid eligible hospitals or CAHs who adopt, implement or upgrade certified EHR technology in their first payment year, the meaningful use objectives and associated measures of the Stage 3 criteria specified in paragraph (d) of this section apply beginning with the second payment year, and do not apply to the first payment year.

(c) *Objectives and associated measures in paragraph (d) of this section that rely on measures that count unique patients or actions.*

(1) If a measure (or associated objective) in paragraph (d) of this section references paragraph (c) of this section, then the measure may be calculated by reviewing only the actions for patients whose records are maintained using certified EHR technology. A patient's record is maintained using certified EHR technology if sufficient data was entered in the certified EHR technology to allow the record to be saved, and not rejected due to incomplete data.

(2) If the objective and associated measure does not reference this paragraph (c) of this section, then the measure must be calculated by reviewing all patient records, not just those maintained using certified EHR technology.

(d) *Stage 3 objectives and measures for EPs, eligible hospitals, and CAHs.*

(1) *Protect patient health information.*

(i) *EP protect patient health information.*

(A) *Objective.* Protect electronic protected health information (ePHI) created or maintained by the certified EHR technology (CEHRT) through the implementation of appropriate technical, administrative, and physical safeguards.

(B) *Measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including:

(1) Addressing the security (including encryption) of data stored in CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3),

(2) Implement security updates as necessary, and

(3) Correct identified security deficiencies as part of the EP's risk management process.

(ii) *Eligible hospital/CAH protect patient health information.*

(A) *Objective.* Protect electronic protected health information (ePHI) created or maintained by the certified EHR technology (CEHRT) through the implementation of appropriate technical, administrative, and physical safeguards.

(B) *Measure.* Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including—

(1) Addressing the security (including encryption) of data stored in CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3);

(2) Implement security updates as necessary; and

(3) Correct identified security deficiencies as part of the eligible hospital's or CAH's risk management process.

(2) *Electronic prescribing.*

(i) *EP electronic prescribing.*

(A) *Objective.* Generate and transmit permissible prescriptions electronically (eRx).

(B) *Measure.* Subject to paragraph (c) of this section, more than 80 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using certified EHR technology (CEHRT).

(C) *Exclusions in accordance with paragraph (a)(3) of this section.*

(1) Any EP who writes fewer than 100 permissible prescriptions during the EHR reporting period; or

(2) Any EP who does not have a pharmacy within its organization and there are no pharmacies that accept electronic prescriptions within 10 miles of the EP's practice location at the start of his/her EHR reporting period.

(ii) *Eligible hospital/CAH electronic prescribing.*

(A) *Objective.* Generate and transmit permissible discharge prescriptions electronically (eRx).

(B) *Measure.* Subject to paragraph (c) of this section, more than 25 percent of hospital discharge medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using certified EHR technology (CEHRT).

(C) *Exclusions in accordance with paragraph (b)(3) of this section.* Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of the eligible hospital's or CAH's EHR reporting period.

(3) *Clinical decision support.*

(i) *EP clinical decision support.*

(A) *Objective.* Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

(B) *Measures.*

(1) Implement five clinical decision support interventions related to four or more clinical quality measures (CQMs) at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an EP's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions; and

(2) The EP has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

(C) *Exclusion in accordance with paragraph (a)(3) of this section for paragraph (d)(3)(i)(B)(2) of this section.* An EP who writes fewer than 100 medication orders during the EHR reporting period.

(ii) *Eligible hospital/CAH clinical decision support.*

(A) *Objective.* Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

(B) *Measures.*

(1) Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures (CQMs) related to an eligible hospital or CAH's patient population, the clinical decision support interventions must be related to high-priority health conditions; and

(2) The eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug-

allergy interaction checks for the entire EHR reporting period.

(4) *Computerized provider order entry (CPOE).*

(i) *EP CPOE.*

(A) *Objective.* Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.

(B) *Measures.* Subject to paragraph (c) of this section—

(1) More than 80 percent of medication orders created by the EP during the EHR reporting period are recorded using computerized provider order entry;

(2) More than 60 percent of laboratory orders created by the EP during the EHR reporting period are recorded using computerized provider order entry; and

(3) More than 60 percent of diagnostic imaging orders created by the EP during the EHR reporting period are recorded using computerized provider order entry.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.*

(1) For the measure specified in paragraph (d)(4)(i)(B)(1) of this section, any EP who writes fewer than 100 medication orders during the EHR reporting period.

(2) For the measure specified in paragraph (d)(4)(i)(B)(2) of this section, any EP who writes fewer than 100 laboratory orders during the EHR reporting period.

(3) For the measure specified in paragraph (d)(4)(i)(B)(3) of this section, any EP who writes fewer than 100 diagnostic imaging orders during the EHR reporting period.

(ii) *Eligible hospital and CAH CPOE.*

(A) *Objective.* Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed healthcare professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.

(B) *Measures.* Subject to paragraph (c) of this section, more than—

(1) Eighty percent of medication orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department

(POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry;

(2) Sixty percent of laboratory orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry; and

(3) Sixty percent of diagnostic imaging orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using computerized provider order entry.

(5) *Patient electronic access to health information.*

(i) *EP patient electronic access to health information.*

(A) *Objective.* The EP provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an application-program interface (API), within 24 hours of its availability.

(B) *Measures. EPs must meet the following two measures:*

(1) For more than 80 percent of all unique patients seen by the EP—

(i) The patient (or patient authorized representatives) is provided access to view online, download, and transmit their health information within 24 hours of its availability to the provider; or

(ii) The patient (or patient authorized representatives) is provided access to an ONC-certified application-program interface (API) that can be used by third-party applications or devices to provide patients (or patient authorized representatives) access to their health information, within 24 hours of its availability to the provider.

(2) The EP must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients seen by the EP during the EHR reporting period.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.*

(1) Any EP who has no office visits during the reporting period may exclude from the measures specified in paragraphs (d)(7)(i)(B)(1) and (B)(2) of this section.

(2) Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in

paragraphs (d)(7)(i)(B)(1) and (2) of this section.

(ii) *Eligible hospital and CAH patient electronic access to health information.*

(A) *Objective.* The eligible hospital or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an application-program interface (API), within 24 hours of its availability.

(B) *Measures.* Eligible hospitals and CAHs must meet the following two measures:

(1) For more than 80 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23)—

(i) The patient (or patient authorized representatives) is provided access to view online, download, and transmit their health information within 24 hours of its availability to the provider; or

(ii) The patient (or patient authorized representatives) is provided access to an ONC-certified application-program interface (API) that can be used by third-party applications or devices to provide patients (or patient authorized representatives) access to their health information, within 24 hours of its availability to the provider.

(2) The eligible hospital or CAH must use clinically relevant information from CEHRT to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

(C) *Exclusion in accordance with paragraph (b)(3) of this section.* Any eligible hospital or CAH that is located in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period is excluded from the measures specified in paragraphs (d)(7)(ii)(B)(1) and (2) of this section.

(6) *Coordination of care through patient engagement.*

(i) *EP coordination of care through patient engagement.*

(A) *Objective.* Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.

(B) *Measures.* In accordance with paragraph (a)(2) of this section, an EP must satisfy 2 out of the 3 following measures in paragraphs (d)(5)(i)(B)(1), (2), and (3) of this section except those measures for which an EP qualifies for

an exclusion under paragraph (a)(3) of this section.

(1) During the EHR reporting period, more than 25 percent of all unique patients seen by the EP actively engage with the electronic health record made accessible by the provider. An EP may meet measure specified in paragraph (d)(5)(i)(B)(1) of this paragraph by either—

(i) More than 25 percent of all unique patients (or patient-authorized representatives) seen by the EP during the EHR reporting period view, download or transmit to a third party their health information; or

(ii) More than 25 percent of all unique patients (or patient-authorized representatives) seen by the EP during the EHR reporting period access their health information through the use of an ONC-certified API that can be used by third-party applications or devices.

(2) For more than 35 percent of all unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient.

(3) Patient generated health data or data from a nonclinical setting is incorporated into the certified EHR technology for more than 15 percent of all unique patients seen by the EP during the EHR reporting period.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.*

(1) Any EP who has no office visits during the reporting period may exclude from the measures specified in paragraphs (d)(5)(i)(B)(1), (B)(2) and (B)(3) of this section.

(2) Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(5)(i)(B)(1), (B)(2) and (B)(3) of this section.

(i) *Eligible hospital and CAH coordination of care through patient engagement.*

(A) *Objective.* Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.

(B) *Measures.* In accordance with paragraph (b)(2) of this section, an eligible hospital or CAH must satisfy 2 of the 3 following measures in paragraph (d)(5)(ii)(B)(1), (2), and (3) of this section, except those measures for which an eligible hospital or CAH

qualifies for an exclusion under paragraph (b)(3) of this section.

(1) During the EHR reporting period, more than 25 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the electronic health record made accessible by the provider. An eligible hospital or CAH may meet the measure specified in paragraph (d)(5)(ii)(B)(1) of this section by having—

(i) More than 25 percent of all unique patients (or patient-authorized representatives) discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period view, download or transmit to a third party their health information; or

(ii) More than 25 percent of all unique patients (or patient-authorized representatives) discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period access their health information through the use of an ONC-certified API that can be used by third-party applications or devices.

(2) For more than 35 percent of all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of CEHRT to the patient (or their authorized representatives), or in response to a secure message sent by the patient.

(3) Patient generated health data or data from a non-clinical setting is incorporated into the certified EHR technology for more than 15 percent of unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

(C) *Exclusions under paragraph (b)(3) of this section.*

(1) Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(5)(ii)(B)(1), (B)(2), and (B)(3) of this section.

(7) *Health information exchange.*

(i) *EP health information exchange.*

(A) *Objective.* The EP provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care

information from other providers into their EHR using the functions of certified EHR technology.

(B) *Measures.* In accordance with paragraph (a)(2) of this section, an EP must attest to all 3 measures, but must meet the threshold for 2 of the 3 measures in paragraph (d)(6)(i)(B)(1), (2), and (3), in order to meet the objective. Subject to paragraph (c) of this section—

(1) *Measure 1.* For more than 50 percent of transitions of care and referrals, the EP that transitions or refers their patient to another setting of care or provider of care—

(i) Creates a summary of care record using CEHRT; and

(ii) Electronically exchanges the summary of care record.

(2) *Measure 2.* For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP incorporates into the patient's EHR an electronic summary of care document from a source other than the provider's EHR system.

(3) *Measure 3.* For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP performs clinical information reconciliation. The EP must implement clinical information reconciliation for the following three clinical information sets:

(i) *Medication.* Review of the patient's medication, including the name, dosage, frequency, and route of each medication.

(ii) *Medication allergy.* Review of the patient's known allergic medications.

(iii) *Current problem list.* Review of the patient's current and active diagnoses.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.* An EP must be excluded when any of the following occur:

(1) An EP neither transfers a patient to another setting nor refers a patient to another provider during the EHR reporting period must be excluded from paragraph (d)(6)(i)(B)(1) of this section.

(2) Any EP for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period may be excluded from paragraphs (d)(6)(i)(B)(2) and (d)(6)(i)(B)(3) of this section.

(3) Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units

with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(6)(i)(B)(1), (B)(2) and (B)(3) of this section.

(ii) *Eligible hospitals and CAHs health information exchange.*

(A) *Objective.* The eligible hospital or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a their new patient, and incorporates summary of care information from other providers into EHR using the functions of certified EHR technology.

(B) *Measures.* In accordance with paragraph (b)(2) of this section, an eligible hospital or CAH must attest to all three measures, but must meet the threshold for 2 of the 3 measures in paragraph (d)(6)(ii)(B)(1), (2), and (3). Subject to paragraph (c) of this section—

(1) *Measure 1.* For more than 50 percent of transitions of care and referrals, the eligible hospital or CAH that transitions or refers its patient to another setting of care or provider of care—

(i) Creates a summary of care record using CEHRT; and

(ii) Electronically exchanges the summary of care record.

(2) *Measure 2.* For more than 40 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH incorporates into the patient's EHR an electronic summary of care document from a source other than the provider's EHR system.

(3) *Measure 3.* For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the eligible hospital or CAH performs a clinical information reconciliation. The provider must implement clinical information reconciliation for the following three clinical information sets:

(i) *Medication.* Review of the patient's medication, including the name, dosage, frequency, and route of each medication.

(ii) *Medication allergy.* Review of the patient's known allergic medications.

(iii) *Current problem list.* Review of the patient's current and active diagnoses.

(C) *Exclusions in accordance with paragraph (b)(3) of this section.*

(1) Any eligible hospital or CAH for whom the total of transitions or referrals received and patient encounters in

which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period may be excluded from paragraphs (d)(6)(i)(B)(2) and (d)(6)(i)(B)(3) of this section.

(2) Any eligible hospital or CAH operating in a location that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude from the measures specified in paragraphs (d)(6)(ii)(B)(1), (2) and (3) of this section.

(8) *Public Health and Clinical Data Registry Reporting.*

(i) *EP Public Health and Clinical Data Registry: Reporting objective.*

(A) *Objective.* The EP is in active engagement with a public health agency (PHA) or clinical data registry (CDR) to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

(B) *Measures.* In order to meet the objective under paragraph (d)(8)(i)(A) of this section, an EP must choose from measures 1 through 5 (paragraphs (d)(8)(i)(B)(1) through (d)(8)(i)(B)(5) of this section) and must successfully attest to any combination of three measures. These measures may be met by any combination, including meeting measure specified in paragraph (d)(8)(i)(B)(4) or (5) of this section multiple times, in accordance with applicable law and practice:

(1) *Immunization registry reporting.* The EP is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

(2) *Syndromic surveillance reporting.* The EP is in active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care ambulatory setting.

(3) *Case reporting.* The EP is in active engagement with a public health agency to submit case reporting of reportable conditions.

(4) *Public health registry reporting.* The EP is in active engagement with a public health agency to submit data to public health registries.

(5) *Clinical data registry reporting.* The EP is in active engagement to submit data to a clinical data registry.

(C) *Exclusions in accordance with paragraph (a)(3) of this section.*

(1) Any EP meeting one or more of the following criteria may be excluded from

the immunization registry reporting measure in paragraph (d)(8)(i)(B)(1) of this section if the EP:

(i) Does not administer any immunizations to any of the populations for which data is collected by their jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(ii) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of its EHR reporting period.

(iii) Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data at the start of the EHR reporting period.

(2) Any EP meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure described in paragraph (d)(8)(i)(B)(2) of the section if the EP:

(i) Does not treat or diagnose or directly treat any disease or condition associated with a syndromic surveillance system in the EP's jurisdiction.

(ii) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data at the start of the EHR reporting period.

(3) Any EP meeting one or more of the following criteria may be excluded from the case reporting measure at paragraph (d)(8)(i)(B)(3) of this section if the EP:

(i) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period.

(ii) Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data at the start of the EHR reporting period.

(4) Any EP meeting at least one of the following criteria may be excluded from the public health registry reporting measure specified in paragraph (d)(8)(i)(B)(4) of this section if the EP:

(i) Does not diagnose or directly treat any disease or condition associated with a public health registry in the EP's jurisdiction during the EHR reporting period.

(ii) Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health registry for which the EP is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

(5) Any EP meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure specified in paragraph (d)(8)(i)(B)(5) of this section if the EP:

(i) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period;

(ii) Operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no clinical data registry for which the EP is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

(ii) *Eligible hospital and CAH Public Health and Clinical Data Registry: Reporting objective.*

(A) *Objective.* The eligible hospital or CAH is in active engagement with a public health agency (PHA) or clinical data registry (CDR) to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

(B) *Measures.* In order to meet the objective under paragraph (d)(8)(ii)(A) of this section, an eligible hospital or CAH must choose from measures 1 through 6 (as described in paragraphs (d)(8)(ii)(B)(1) through (d)(8)(ii)(B)(6) of this section) and must successfully attest to any combination of four measures. These measures may be met by any combination, including meeting the measure specified in paragraph (d)(8)(ii)(B)(4) or (5) of this section multiple times, in accordance with applicable law and practice:

(1) *Immunization registry reporting.* The eligible hospital or CAH is in active engagement with a public health agency to submit immunization data and

receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).

(2) *Syndromic surveillance reporting.* The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an emergency or urgent care department (POS 23).

(3) *Case reporting.* The eligible hospital or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions.

(4) *Public health registry reporting.* The eligible hospital or CAH is in active engagement with a public health agency to submit data to public health registries.

(5) *Clinical data registry reporting.* The eligible hospital or CAH is in active engagement to submit data to a clinical data registry.

(6) *Electronic reportable laboratory result reporting.* The eligible hospital or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results.

(C) *Exclusions in accordance with paragraph (b)(3) of this section.*

(1) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure specified in paragraph (d)(8)(ii)(B)(1) of this section if the eligible hospital or CAH:

(i) Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the EHR reporting period.

(ii) Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data at the start of the EHR reporting period.

(2) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure specified in paragraph (d)(8)(ii)(B)(2) of this section if the eligible hospital or CAH:

(i) Does not have an emergency or urgent care department.

(ii) Operates in a jurisdiction for which no public health agency is capable of receiving electronic syndromic surveillance data in the

specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive syndromic surveillance data at the start of the EHR reporting period.

(3) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure specified in paragraph (d)(8)(ii)(B)(3) of this section if the eligible hospital or CAH:

(i) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period.

(ii) Operates in a jurisdiction for which no public health agency is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of their EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic case reporting data at the start of the EHR reporting period.

(4) Any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure specified in paragraph (d)(8)(ii)(B)(4) of this section if the eligible hospital or CAH:

(i) Does not diagnose or directly treat any disease or condition associated with a public health registry in its jurisdiction during the EHR reporting period.

(ii) Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

(5) Any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure specified in paragraph (d)(8)(ii)(B)(5) of this section if the eligible hospital or CAH:

(i) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period.

(ii) Operates in a jurisdiction for which no clinical data registry is

capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no clinical data registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions at the beginning of the EHR reporting period.

(6) Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the electronic reportable laboratory result reporting measure specified in paragraph (d)(8)(ii)(B)(6) of this section if the eligible hospital or CAH:

(i) Does not perform or order laboratory tests that are reportable in its jurisdiction during the EHR reporting period.

(ii) Operates in a jurisdiction for which no public health agency that is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period.

(iii) Operates in a jurisdiction where no public health agency has declared readiness to receive electronic reportable laboratory results at the start of the EHR reporting period.

■ 5. Section 495.8 is amended as follows:

■ A. In paragraph (a) introductory text, by removing the cross-reference “under § 495.6 of this subpart” and adding in its place the cross-reference “under § 495.6 or § 495.7”.

■ B. In paragraph (a)(1)(i)(B), by removing the cross-reference “under § 495.6(d) and § 495.6(e) of this subpart” and adding in its place the cross-reference “under § 495.6 or § 495.7”.

■ C. In paragraph (a)(1)(iii), by removing the cross-reference “in § 495.6 and § 495.8 of this subpart” and adding in its place the cross-reference “in § 495.6 or § 495.7 and § 495.8”.

■ D. In paragraph (a)(2)(i)(B), by removing the cross-reference “under § 495.6” and adding in its place the cross-reference “under § 495.6 or § 495.7”.

■ E. Adding paragraph (a)(2)(i)(E).

■ F. In paragraph (a)(2)(iv), by removing the cross-reference “in § 495.6 and § 495.8 of this subpart” and adding in its place the cross-reference “in § 495.6 or § 495.7 and § 495.8”.

■ G. In paragraph (b)(1)(i)(B), by removing the cross-reference “under § 495.6(f) and § 495.6(g)” and adding in its place the cross-reference “under § 495.6 or § 495.7”.

■ H. Redesignating paragraph (b)(1)(iv) and paragraph (b)(1)(iii).

■ I. In newly redesignated paragraph (b)(1)(iii), by removing the cross-

reference “in § 495.6 and § 495.8 of this subpart” and adding in its place the cross-reference “in § 495.6 or § 495.7 and § 495.8”.

■ J. In paragraph (b)(2)(i)(B), by removing the cross-reference “under § 495.6” and adding in its place the cross-reference “under § 495.6 or § 495.7”.

■ K. Adding paragraph (b)(2)(i)(E).

The additions read as follows:

§ 495.8 Demonstration of meaningful use criteria.

(a) * * *

(2) * * *

(i) * * *

(E) For 2017 only, an EP may attest to the following:

(1) Stage 1 objectives and measures outlined at § 495.6 if the EP has never before demonstrated meaningful use, or if the EP previously demonstrated meaningful use for the first time in 2015 or 2016.

(2) Stage 2 objectives and measures outlined at § 495.6 if the EP previously demonstrated meaningful use for any year prior to 2017.

(3) Stage 3 objectives and measures outlined at § 495.7 if the EP has never before demonstrated meaningful use or if the EP has demonstrated meaningful use for any year prior to 2017.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(E) For 2017 only, an eligible hospital or CAH may attest to the following:

(1) Stage 1 objectives and measures outlined at § 495.6 if the eligible hospital or CAH has never before demonstrated meaningful use, or if the eligible hospital or CAH previously demonstrated meaningful use for the first time in 2015 or 2016.

(2) Stage 2 objectives and measures outlined at § 495.6 if the eligible hospital or CAH previously demonstrated meaningful use for any year prior to 2017.

(3) Stage 3 objectives and measures outlined at § 495.7 if the eligible hospital or CAH has never before demonstrated meaningful use or if the eligible hospital or CAH has demonstrated meaningful use for any year prior to 2017.

* * * * *

■ 6. Section 495.316 is amended by revising paragraph (c) introductory text and adding paragraphs (d)(2)(iii), (f), (g), and (h) to read as follows:

§ 495.316 State monitoring and reporting regarding activities required to receive an incentive payment.

* * * * *

(c) Subject to § 495.332 and § 495.352, the State is required to submit to CMS annual reports, in the manner prescribed by CMS, on the following:

* * * * *

(d) * * *

(2) * * *

(iii) Subject to § 495.332, the State may propose a revised definition for Stage 3 of meaningful use of certified EHR technology, subject to CMS prior approval, but only with respect to the public health and clinical data registry reporting objective described in § 495.7(d)(8).

* * * * *

(f) Each State must submit to CMS the annual report described in paragraph (c) of this section within 45 days of the end of the second quarter of the Federal fiscal year.

(g) The State must, on a quarterly basis and in the manner prescribed by CMS, submit a report(s) on the following:

(1) The State and payment year to which the quarterly report pertains.

(2) Subject to paragraph (h)(2) of this section, provider-level attestation data for each EP and eligible hospital that attests to demonstrating meaningful use for each payment year beginning with 2013.

(h)(1) Subject to paragraph (h)(2) of this section, the quarterly report described in paragraph (g) of this section must include the following for each EP and eligible hospital:

(i) The payment year number.

(ii) The provider's National Provider Identifier or CCN, as appropriate.

(iii) Attestation submission date.

(iv) The state qualification.

(v) The state qualification date, which is the beginning date of the provider's EHR reporting period for which it demonstrated meaningful use.

(vi) The State disqualification, if applicable.

(vii) The State disqualification date, which is the beginning date of the provider's EHR reporting period to which the provider attested but for which it did not demonstrate meaningful use, if applicable.

(2) The quarterly report described in paragraph (g) of this section is not required to include information on EPs who are eligible for the Medicaid EHR incentive program on the basis of being a nurse practitioner, certified nurse-midwife or physician assistant.

■ 7. Section 495.352 is revised to read as follows:

§ 495.352 Reporting requirements.

(a) Each State must submit to HHS on a quarterly basis a progress report, in the

manner prescribed by HHS, documenting specific implementation and oversight activities performed during the quarter, including progress in implementing the State's approved Medicaid HIT plan.

(b) The quarterly progress reports must include, but need not be limited to providing, updates on the following:

- (1) State system implementation dates.
- (2) Provider outreach.
- (3) Auditing.
- (4) State-specific State Medicaid HIT Plan tasks.
- (5) State staffing levels and changes.
- (6) The number and type of providers that qualified for an incentive payment on the basis of having adopted, implemented or upgraded certified EHR technology and the amounts of incentive payments.
- (7) The number and type of providers that qualified for an incentive payment on the basis of having demonstrated that they are meaningful users of certified EHR technology and the amounts of incentive payments.

Dated: March 10, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: March 18, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015-06685 Filed 3-20-15; 3:00 pm]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 170

RIN 0991-AB93

2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking with comment period.

SUMMARY: This notice of proposed rulemaking introduces a new edition of certification criteria (the 2015 Edition health IT certification criteria or "2015 Edition"), proposes a new 2015 Edition Base EHR definition, and proposes to

modify the ONC Health IT Certification Program to make it open and accessible to more types of health IT and health IT that supports various care and practice settings. The 2015 Edition would also establish the capabilities and specify the related standards and implementation specifications that Certified Electronic Health Record (EHR) Technology (CEHRT) would need to include to, at a minimum, support the achievement of meaningful use by eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) under the Medicare and Medicaid EHR Incentive Programs (EHR Incentive Programs) when such edition is required for use under these programs.

DATES: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, no later than 5 p.m. on May 29, 2015.

ADDRESSES: You may submit comments, identified by RIN 0991-AB93, by any of the following methods (please do not submit duplicate comments). Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

- *Federal eRulemaking Portal:* Follow the instructions for submitting comments. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word. <http://www.regulations.gov>.

- *Regular, Express, or Overnight Mail:* Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention: 2015 Edition Health IT Certification Criteria Proposed Rule, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave SW., Washington, DC 20201. Please submit one original and two copies.

- *Hand Delivery or Courier:* Office of the National Coordinator for Health Information Technology, Attention: 2015 Edition Health IT Certification Criteria Proposed Rule, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave SW., Washington, DC 20201. Please submit one original and two copies. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

Enhancing the Public Comment Experience: To facilitate public comment on this proposed rule, a copy will be made available in Microsoft Word format. We believe this version

will make it easier for commenters to access and copy portions of the proposed rule for use in their individual comments. Additionally, a separate document will be made available for the public to use to provide comments on the proposed rule. This document is meant to provide the public with a simple and organized way to submit comments on the certification criteria, associated standards and implementation specifications, and respond to specific questions posed in the preamble of the proposed rule. While use of this document is entirely voluntary, we encourage commenters to consider using the document in lieu of unstructured comments or to use it as an addendum to narrative cover pages. Roughly 30% of the public comments submitted to our past two editions of certification criteria proposed rules used the provided template, which greatly assisted in our ability to rapidly process and more accurately categorize public comments. Because of the technical nature of this proposed rule, we believe that use of the document may facilitate our review and understanding of the comments received. The Microsoft Word version of the proposed rule and the document that can be used for providing comments can be found at <http://www.regulations.gov> as part of this proposed rule's docket and on ONC's Web site (<http://www.healthit.gov>).

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. Such information includes, but is not limited to: a person's social security number; date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered proprietary. We will post all comments that are received before the close of the comment period at <http://www.regulations.gov>.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> or the Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave SW., Washington,