

Knox-Keene Regulatory Requirements

The Knox-Keene Act (the “Act”) is voluminous and highly detailed. A complete outline of its requirements would fill a book. Nevertheless, there are certain requirements under the Act that necessitate substantial compliance planning prior to forming or operating a health care service plan licensed under the Act (a “Plan”). The following presents a concise overview of these requirements.

License Verifications

A Plan must ensure that (1) all facilities, including clinics, hospitals, and skilled nursing facilities, it contracts with or otherwise utilizes are licensed by the State Department of Public Health;¹ (2) all personnel employed or under contract are licensed or registered where required by law;² and (3) all equipment and persons operating such equipment are licensed or registered as and when required by law.³ While this requirement is straightforward, it will require significant administrative work to gather and track the required licensing and/or registration information, and will require implementing standard contractual language in all contracts with or affecting the aforementioned facilities, individuals, and equipment to require that they are and remain fully licensed during the term of the contract.

Dispute Resolution Mechanism

Each contract entered into by the Plan with any subscriber/enrollee or any persons furnishing services, equipment, or facilities in connection with or to the Plan must contain provisions requiring a fast, fair, and cost-effective dispute resolution mechanism under which providers, subscriber/enrollees, and contracting parties may submit disputes to the Plan.⁴ The dispute resolution mechanisms must contain provisions to ensure it is accessible to non-contracted providers,⁵ and the Plan must submit an annual reporting detailing the number of disputes and its resolution.⁶ Accordingly, a Plan must develop its dispute resolution mechanism prior to beginning operations, including developing policies and procedures, drafting forms, establishing phone number and email complaint hotlines, and hiring staff to carry out the program.

¹ Cal. Hlth. & Safety Code § 1367(a).

² Cal. Hlth. & Safety Code § 1367(b).

³ Cal. Hlth. & Safety Code § 1367(c).

⁴ Cal. Hlth. & Safety Code § 1367(h)(1).

⁵ Cal. Hlth. & Safety Code § 1367(h)(2).

⁶ Cal. Hlth. & Safety Code § 1367(h)(3).

Required Services

The Plan must create a network and price its product in view of the need to provide the following services: (1) physician services, (2) hospital inpatient and ambulatory care services, (3) diagnostic laboratory and diagnostic/therapeutic radiation services, (4) home health services, (5) preventative health services, (6) emergency care services including ambulance transport services, and (7) hospice care.⁷ This requirement is vital for determining the types of providers and facilities the plan must contract with *prior* to beginning operations.

Compliance With Patient Protection and Affordable Care Act Requirements

Each Plan must also comply with a host of requirements imposed by the Patient Protection and Affordable Care Act (the “ACA”), including the following requirements.

- A Plan may not set an annual life-time limits on benefits in accordance with 42 U.S.C. § 300gg-11.⁸

- A Plan must offer the preventative care services required by 42 U.S.C. § 300gg-13.⁹

- A Plan must hit a minimum medical loss ration (“MLR”), meaning the percentage of premiums spent on “reimbursement for clinical services provided to enrollees and “for activities that improve health care quality”, of at least 85% for large group plans and 80% for small group and individual market plans; otherwise, the Plan must reimburse its enrollees any amounts it retained in excess of the MLR for any coverage year.¹⁰ Further, a Plan must comply with all regulations issued by the Federal government relating to MLR, including regulations issued pursuant to 42 U.S.C. § 300-gg18, e.g., 45 C.F.R. Part 158.¹¹ A Plan should begin creating a basis for expenses that fall under “activities that improve health care quality” because this definition will allow the Plan to define most of its operational costs, e.g., salaries and benefits, office expenses, etc., as contributing to the MLR and thus reducing or eliminating the need to pay a reimbursement for failure to hit the MLR.

- A Plan must offer the “essential health benefits” required by the ACA, which include “ambulatory patient services, emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services, including behavioral health treatment, prescription drugs, rehabilitative and habilitative services and devices, laboratory services, preventive and wellness services and chronic disease

⁷ Cal. Hlth. & Safety Code § 1367(i) (requires provision of all services listed at Cal. Hlth. & Safety Code § 1345(b)).

⁸ Cal. Hlth. & Safety Code § 1367.001.

⁹ Cal. Hlth. & Safety Code § 1367.002.

¹⁰ Cal. Hlth. & Safety Code § 1367.003.

¹¹ *Id.*

management, and pediatric services, including oral and vision care.”¹² A Plan must also offer alcoholism and chemical dependency treatment.¹³ Further, a Plan must offer all of the benefits covered by California’s benchmark plan, the Kaiser Foundation Health Plan Small Group HMO 30, as offered during the first quarter of 2012, which include all of the basic health care services discussed above under “Required Services” and the following health benefits mandated to be covered by the Plan pursuant to state law:¹⁴

- Preventive services for children (see California Health and Safety Code Sections (“Code”) 1367.002, 1367.06, 1367.3, and 1367.35);
- Prescription drug coverage for contraceptives (see Code Section 1367.25);
- AIDS vaccines (when created and approved), HIV testing, and organ transplants for HIV patients (see Code Sections 1367.45, 1367.46, and 1374.17);
- Diabetes treatments (see Code Section 1367.51);
- Alpha fetoprotein testing (see Code Section 1367.54);
- Breast cancer screening (see Code Section 1367.6);
- Prosthetics for laryngectomy (see Code Section 1367.61);
- Maternity hospital stays (see Code Section 1367.62);
- Reconstructive surgery (see Code Section 1367.63);
- Mastectomies (see Code Section Section 1367.635);
- Prostate cancer screening (see Code Section 1367.64);
- Mammography (see Code Section 1367.65);
- Cervical cancer screening (see Code Section 1367.66);
- Cancer screening tests (see Code Section 1367.665);
- Osteoporosis screening and treatment (see Code Section 1367.67);
- Jaw bone surgery (see Section 1367.68);
- Coverage of anesthesia services related to dental surgery performed in a hospital or clinic due to an enrollee’s underlying medical condition (see Code Section 1367.71);
- Conditions attributable to diethylstilbestrol (see Code Section 1367.9);
- Hospice care (see Code Section 1368.2);
- Clinical trials for cancer treatment (see Code Section 1370.6);
- Emergency response ambulance or ambulance transport services (see Code Section 1371.5);
- Sterilization operations and procedures (see Code Section 1373(b));
- Inpatient hospital and ambulatory maternity services (see Code Section 1373.4);
- Phenylketonuria (see Code Section 1374.56); and,
- Autism and behavioral health services provided in accord with California’s mental health parity laws (see Code Sections 1374.72 and 1374.73).

¹² Cal. Hlth. & Safety Code § 1367.005(a)(1).

¹³ Cal. Hlth. & Safety Code § 1367.2.

¹⁴ Cal. Hlth. & Safety Code § 1367.005(a)(2).

Again, the purpose of providing this lengthy list is to illustrate the sheer number of services a Plan must contract for and be able to provide to its enrollees. Since a Plan must be ready to operate prior to receiving its license (the Act's licensing procedures under Code Section 1351 requires a Plan to be able to provide a statement regarding the health care delivery capabilities of the Plan, the arrangements and methods by which care will be provided, i.e., through IPAs or through direct hiring of physicians, and the number of contracted hospital beds, in order to receive licensure), the Plan must contract for all of these services prior to or at least during the licensing process to ensure it is operational immediately upon receipt of its license. This will require significant "leg-work" identifying providers and facilities, and significant legal work negotiating and executing contracts with all such providers and facilities.

- A Plan must limit out-of-pocket maximum expenses for enrollees as prescribed by Federal law. In 2015 the limits are \$6,600 for an individual plan and \$13,200 for a family plan.¹⁵ A Plan must place these numbers at the forefront of its analysis with respect to designing premium prices and in estimating its financial performance.

- For plans offered to small employers the deductible is capped at \$2,000 for an individual plan, and \$4,000 for all other plans (with such amounts being indexed to increase in accordance with 42 U.S.C. § 18022).¹⁶

- All plans must comply with the actuarial levels established by the ACA, e.g., Bronze, Silver, Gold, and Platinum, with regards to percentage of costs covered by the Plan.¹⁷ Again, these values will be essential in determining the pricing of plans and projecting the Plan's financial performance.

Utilization Review

A Plan's utilization review methods ("UR Program") must comply with the following requirements (this is a non-exhaustive list) and must be submitted and approved by the Department of Managed Health Care ("DMHC"):¹⁸ (1) the UR Program must be governed by written policies and procedures that are: (a) developed with the involvement of actively practicing health care providers, (b) consistent with sound clinical principles, (c) evaluated and updated annually, (d) disclosed to any provider or enrollee whose treatment or services are modified, delayed or denied based upon such policies and procedures, and (e) are available to the public upon request; (2) the Plan must employ or contract with a licensed physician or osteopath to serve as medical director of the UR Program and to ensure compliance with these requirements; (3) only a licensed physician or other licensed health care provider who is competent to evaluate specific clinical issues raised by the specific health care services being subject to review may deny or modify requests for authorization; and (4) all decisions to approve, modify, or deny care on a prospective basis must be made within five business days of the

¹⁵ Cal. Hlth. & Safety Code § 1367.006.

¹⁶ Cal. Hlth. & Safety Code § 1367.007.

¹⁷ Cal. Hlth. & Safety Code §§ 1367.008, 1367.009.

¹⁸ Cal. Hlth. & Safety Code § 1367.01.

Plan's receipt of information reasonably necessary to make its decision, or in the case of retrospective review, within thirty days of receipt of the information, or in the case of an enrollee facing imminent potential loss of life, limb, or major bodily function, within seventy-two hours.

Further, a Plan must submit a report to the DMHC detailing how it utilizes economic profiling, defined as an evaluation based in whole or part on the economic costs or utilization of services associated with medical care, and how such profiling still allows medical providers to make medical decision "unhindered by fiscal or administrative management."¹⁹

These UR Program requirements will necessitate significant work prior to a Plan becoming operational, including (1) development of the guiding policies and procedures, (2) hiring of a medical director and other medical reviewers, and (3) development of appropriate economic profiling tools.

Access to Care

A Plan must meet the access to care requirements provided at 28 CCR 1300.67.2.2,²⁰ which require a Plan to have a network adequate to provide care "in a timely manner appropriate for the nature of the enrollee's condition consistent with good professional practice." Further, the following types of services have specific timeliness standards: (1) 48-hours for urgent care not requiring prior authorization, (2) 96-hours for urgent care requiring prior authorization, (3) 10-business days for non-urgent primary care visits, (4) 15-business days for non-urgent specialist visits, (5) 10-business days for non-urgent appointments with non-physician mental health providers, and (6) 15-business days for non-urgent ancillary services for treatment or diagnosis. Due to these statutorily prescribed waiting times, a Plan must ensure its network is adequate prior to operation, otherwise the Plan may find itself in violation of these regulations shortly after beginning operation, which would subject the young Plan to fines and other penalties. Further, all contracts between a Plan and its providers must require compliance with these timelines, which again necessitates planning for compliance with these regulations *prior* to being licensed or becoming fully operational.²¹

Lastly, with respect to access, a Plan must ensure that all of its vital documents (which includes, among others, its applications, consent forms, letters containing eligibility and participation criteria, notices pertaining to denial, reduction, modification, or termination of services and benefits, or the right to file an appeal or grievance) are available in: (1) for plans with 1,000,000 or more enrollees, English plus the top two languages spoken by its beneficiaries, and any other language preferred by at least 15,000 or .75%, whichever is less, of its enrollees; (2) for plans with 300,000 or more enrollees, English plus the top other language spoken by its beneficiaries, and any other language preferred by at least 6,000 or 1%, whichever is less, of its enrollees; and (3) for plans

¹⁹ Cal. Hlth. & Safety Code § 1367.02.

²⁰ See Cal. Hlth. & Safety Code § 1367.03.

²¹ Cal. Hlth. & Safety Code § 1367.03(f)(1).

with less than 300,000 enrollees, English plus any other language preferred by at least 3,000 or 5%, whichever is less, of its enrollees.²² Due to this requirement, a Plan must translate and create copies of all of its vital documents prior to becoming operational.

Grievance System

A Plan must develop a grievance system, and submit such system to the DMHC for approval.²³ The grievance system must provide written responses to enrollee grievances, and for grievances involving health care services, must provide the criteria and clinical reasoning employed in responding to the grievance. This requirement will necessitate the creation of governing policies and procedures, forms, dedicated phone and/or email resources for receiving grievances, and hiring and training of staff prior to a Plan becoming operational.

²² Cal. Hlth. & Safety Code § 1367.04.

²³ Cal. Hlth. & Safety Code § 1368.