

§ 1367.01. Written policies and procedures for review and approval, modification, delay or denial of services; Medical director to ensure compliance; Compliance review

(a) A health care service plan and any entity with which it contracts for services that include utilization review or utilization management functions, that prospectively, retrospectively, or concurrently reviews and approves, modifies, delays, or denies, based in whole or in part on medical necessity, requests by providers prior to, retrospectively, or concurrent with the provision of health care services to enrollees, or that delegates these functions to medical groups or independent practice associations or to other contracting providers, shall comply with this section.

(b) A health care service plan that is subject to this section shall have written policies and procedures establishing the process by which the plan prospectively, retrospectively, or concurrently reviews and approves, modifies, delays, or denies, based in whole or in part on medical necessity, requests by providers of health care services for plan enrollees. These policies and

procedures shall ensure that decisions based on the medical necessity of proposed health care services are consistent with criteria or guidelines that are supported by clinical principles and processes. These criteria and guidelines shall be developed pursuant to Section 1363.5. These policies and procedures, and a description of the process by which the plan reviews and approves, modifies, delays, or denies requests by providers prior to, retrospectively, or concurrent with the provision of health care services to enrollees, shall be filed with the director for review and approval, and shall be disclosed by the plan to providers and enrollees upon request, and by the plan to the public upon request.

(c) A health care service plan subject to this section, except a plan that meets the requirements of Section 1351.2, shall employ or designate a medical director who holds an unrestricted license to practice medicine in this state issued pursuant to Section 2050 of the Business and Professions Code or pursuant to the Osteopathic Act, or, if the plan is a specialized health care service plan, a clinical director with California licensure in a clinical area appropriate to the type of care provided by the specialized health care service plan. The medical director or clinical director shall ensure that the process by which the plan reviews and approves, modifies, or denies, based in whole or in part on medical necessity, requests by providers prior to, retrospectively, or concurrent with the provision of health care services to enrollees, complies with the requirements of this section.

(d) If health plan personnel, or individuals under contract to the plan to review requests by providers, approve the provider's request, pursuant to subdivision (b), the decision shall be communicated to the provider pursuant to subdivision (h).

(e) No individual, other than a licensed physician or a licensed health care professional who is competent to evaluate the specific clinical issues involved in the health care services requested by the provider, may deny or modify requests for authorization of health care services for an enrollee for reasons of medical necessity. The decision of the physician or other health care professional shall be communicated to the provider and the enrollee pursuant to subdivision (h).

(f) The criteria or guidelines used by the health care service plan to determine whether to approve, modify, or deny requests by providers prior to, retrospectively, or concurrent with, the provision of health care services to enrollees shall be consistent with clinical principles and processes. These criteria and guidelines shall be developed pursuant to the requirements of Section 1363.5.

(g) If the health care service plan requests medical information from providers in order to determine whether to approve, modify, or deny requests for authorization, the plan shall request only the information reasonably necessary to make the determination.

(h) In determining whether to approve, modify, or deny requests by providers prior to, retrospectively, or concurrent with the provision of health care services to enrollees, based in whole or in part on medical necessity, a health care service plan subject to this section shall meet the following requirements:

- (1) Decisions to approve, modify, or deny, based on medical necessity, requests by providers prior to, or concurrent with the provision of health care

services to enrollees that do not meet the requirements for the time period for review required by paragraph (2), shall be made in a timely fashion appropriate for the nature of the enrollee's condition, not to exceed five business days from the plan's receipt of the information reasonably necessary and requested by the plan to make the determination. In cases where the review is retrospective, the decision shall be communicated to the individual who received services, or to the individual's designee, within 30 days of the receipt of information that is reasonably necessary to make this determination, and shall be communicated to the provider in a manner that is consistent with current law. For purposes of this section, retrospective reviews shall be for care rendered on or after January 1, 2000.

(2) When the enrollee's condition is such that the enrollee faces an imminent and serious threat to the enrollee's health, including, but not limited to, the potential loss of life, limb, or other major bodily function, or the normal timeframe for the decisionmaking process, as described in paragraph (1), would be detrimental to the enrollee's life or health or could jeopardize the enrollee's ability to regain maximum function, decisions to approve, modify, or deny requests by providers prior to, or concurrent with, the provision of health care services to enrollees, shall be made in a timely fashion appropriate for the nature of the enrollee's condition, not to exceed 72 hours or, if shorter, the period of time required under Section 2719 of the federal Public Health Service Act (42 U.S.C. Sec. 300gg-19) and any subsequent rules or regulations issued thereunder, after the plan's receipt of the information reasonably necessary and requested by the plan to make the determination. Nothing in this section shall be construed to alter the requirements of subdivision (b) of Section 1371.4. Notwithstanding Section 1371.4, the requirements of this division shall be applicable to all health plans and other entities conducting utilization review or utilization management.

(3) Decisions to approve, modify, or deny requests by providers for authorization prior to, or concurrent with, the provision of health care services to enrollees shall be communicated to the requesting provider within 24 hours of the decision. Except for concurrent review decisions pertaining to care that is underway, which shall be communicated to the enrollee's treating provider within 24 hours, decisions resulting in denial, delay, or modification of all or part of the requested health care service shall be communicated to the enrollee in writing within two business days of the decision. In the case of concurrent review, care shall not be discontinued until the enrollee's treating provider has been notified of the plan's decision and a care plan has been agreed upon by the treating provider that is appropriate for the medical needs of that patient.

(4) Communications regarding decisions to approve requests by providers prior to, retrospectively, or concurrent with the provision of health care services to enrollees shall specify the specific health care service approved. Responses regarding decisions to deny, delay, or modify health care services requested by providers prior to, retrospectively, or concurrent with the provision of health care services to enrollees shall be communicated to the enrollee in writing, and to providers initially by telephone or facsimile, except with regard to decisions rendered retrospectively, and then in writing,

and shall include a clear and concise explanation of the reasons for the plan's decision, a description of the criteria or guidelines used, and the clinical reasons for the decisions regarding medical necessity. Any written communication to a physician or other health care provider of a denial, delay, or modification of a request shall include the name and telephone number of the health care professional responsible for the denial, delay, or modification. The telephone number provided shall be a direct number or an extension, to allow the physician or health care provider easily to contact the professional responsible for the denial, delay, or modification. Responses shall also include information as to how the enrollee may file a grievance with the plan pursuant to Section 1368, and in the case of Medi-Cal enrollees, shall explain how to request an administrative hearing and aid paid pending under Sections 51014.1 and 51014.2 of Title 22 of the California Code of Regulations.

(5) If the health care service plan cannot make a decision to approve, modify, or deny the request for authorization within the timeframes specified in paragraph (1) or (2) because the plan is not in receipt of all of the information reasonably necessary and requested, or because the plan requires consultation by an expert reviewer, or because the plan has asked that an additional examination or test be performed upon the enrollee, provided the examination or test is reasonable and consistent with good medical practice, the plan shall, immediately upon the expiration of the timeframe specified in paragraph (1) or (2) or as soon as the plan becomes aware that it will not meet the timeframe, whichever occurs first, notify the provider and the enrollee, in writing, that the plan cannot make a decision to approve, modify, or deny the request for authorization within the required timeframe, and specify the information requested but not received, or the expert reviewer to be consulted, or the additional examinations or tests required. The plan shall also notify the provider and enrollee of the anticipated date on which a decision may be rendered. Upon receipt of all information reasonably necessary and requested by the plan, the plan shall approve, modify, or deny the request for authorization within the timeframes specified in paragraph (1) or (2), whichever applies.

(6) If the director determines that a health care service plan has failed to meet any of the timeframes in this section, or has failed to meet any other requirement of this section, the director may assess, by order, administrative penalties for each failure. A proceeding for the issuance of an order assessing administrative penalties shall be subject to appropriate notice to, and an opportunity for a hearing with regard to, the person affected, in accordance with subdivision (a) of Section 1397. The administrative penalties shall not be deemed an exclusive remedy for the director. These penalties shall be paid to the Managed Care Administrative Fines and Penalties Fund and shall be used for the purposes specified in Section 1341.45.

(i) A health care service plan subject to this section shall maintain telephone access for providers to request authorization for health care services.

(j) A health care service plan subject to this section that reviews requests by providers prior to, retrospectively, or concurrent with, the provision of health care services to enrollees shall establish, as part of the quality assurance program required by Section 1370, a process by which the plan's compliance

with this section is assessed and evaluated. The process shall include provisions for evaluation of complaints, assessment of trends, implementation of actions to correct identified problems, mechanisms to communicate actions and results to the appropriate health plan employees and contracting providers, and provisions for evaluation of any corrective action plan and measurements of performance.

(k)(1) A health care service plan, including a specialized health care service plan that uses an artificial intelligence, algorithm, or other software tool for the purpose of utilization review or utilization management functions, based in whole or in part on medical necessity, or that contracts with or otherwise works through an entity that uses an artificial intelligence, algorithm, or other software tool for the purpose of utilization review or utilization management functions, based in whole or in part on medical necessity, shall comply with this section and shall ensure all of the following:

(A) The artificial intelligence, algorithm, or other software tool bases its determination on the following information, as applicable:

- (i) An enrollee's medical or other clinical history.
- (ii) Individual clinical circumstances as presented by the requesting provider.
- (iii) Other relevant clinical information contained in the enrollee's medical or other clinical record.

(B) The artificial intelligence, algorithm, or other software tool does not base its determination solely on a group dataset.

(C) The artificial intelligence, algorithm, or other software tool's criteria and guidelines complies with this chapter, including, but not limited to, Section 1363.5 and applicable state and federal law.

(D) The artificial intelligence, algorithm, or other software tool does not supplant health care provider decisionmaking.

(E) The use of the artificial intelligence, algorithm, or other software tool does not discriminate, directly or indirectly, against enrollees in violation of state or federal law.

(F) The artificial intelligence, algorithm, or other software tool is fairly and equitably applied, including in accordance with any applicable regulations and guidance issued by the federal Department of Health and Human Services.

(G) The artificial intelligence, algorithm, or other software tool is open to inspection for audit or compliance reviews by the department pursuant to Section 1381 and by the State Department of Health Care Services pursuant to applicable state and federal law.

(H) Disclosures pertaining to the use and oversight of the artificial intelligence, algorithm, or other software tool are contained in the written policies and procedures, as required by subdivision (b).

(I) The artificial intelligence, algorithm, or other software tool's performance, use, and outcomes are periodically reviewed and revised to maximize accuracy and reliability.

(J) Patient data is not used beyond its intended and stated purpose, consistent with the Confidentiality of Medical Information Act (Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code) and the federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191), as applicable.

(K) The artificial intelligence, algorithm, or other software tool does not directly or indirectly cause harm to the enrollee.

(2) Notwithstanding paragraph (1), the artificial intelligence, algorithm, or other software tool shall not deny, delay, or modify health care services based, in whole or in part, on medical necessity. A determination of medical necessity shall be made only by a licensed physician or a licensed health care professional competent to evaluate the specific clinical issues involved in the health care services requested by the provider, as provided in subdivision (e), by reviewing and considering the requesting provider's recommendation, the enrollee's medical or other clinical history, as applicable, and individual clinical circumstances.

(3) For purposes of this subdivision, "artificial intelligence" means an engineered or machine-based system that varies in its level of autonomy and that can, for explicit or implicit objectives, infer from the input it receives how to generate outputs that can influence physical or virtual environments.

(4) This subdivision shall apply to utilization review or utilization management functions that prospectively, retrospectively, or concurrently review requests for covered health care services.

(5) A health care service plan subject to this subdivision shall comply with applicable federal rules and guidance issued by the federal Department of Health and Human Services regarding the use of artificial intelligence, algorithm, or other software tools. The department and the State Department of Health Care Services may issue guidance to implement this paragraph within one year of the adoption of federal rules or the issuance of guidance by the federal Department of Health and Human Services regarding the use of artificial intelligence, algorithm, or other software tools. Such guidance shall not be subject to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

(6) For purposes of implementing this subdivision, the department and the State Department of Health Care Services may enter into exclusive or nonexclusive contracts, or amend existing contracts, on a bid or negotiated basis. Contracts entered into or amended pursuant to this subdivision shall be exempt from Chapter 6 (commencing with Section 14825) of Part 5.5 of Division 3 of Title 2 of the Government Code, Section 19130 of the Government Code, and Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code, and shall be exempt from the review or approval of any division of the Department of General Services.

(7) This subdivision applies to a Medi-Cal managed care plan only to the extent that the State Department of Health Care Services obtains any necessary federal approvals, and federal financial participation is not otherwise jeopardized.

(l) The director shall review a health care service plan's compliance with this section as part of its periodic onsite medical survey of each plan undertaken pursuant to Section 1380, and shall include a discussion of compliance with this section as part of its report issued pursuant to that section.

(m) This section shall not apply to decisions made for the care or treatment of the sick who depend upon prayer or spiritual means for healing in the practice of religion as set forth in subdivision (a) of Section 1270.

(n) Nothing in this section shall cause a health care service plan to be defined as a health care provider for purposes of any provision of law, including, but not limited to, Section 6146 of the Business and Professions Code, Sections 3333.1 and 3333.2 of the Civil Code, and Sections 340.5, 364, 425.13, 667.7, and 1295 of the Code of Civil Procedure.

HISTORY:

Added Stats 1999 ch 539 § 4 (SB 59).
Amended Stats 2000 ch 1067 § 8 (SB 2094);
Stats 2004 ch 491 § 3 (SB 1347); Stats 2007 ch
196 § 3 (SB 192), effective January 1, 2008;

Stats 2008 ch 607 § 3 (SB 1379), effective
September 30, 2008; Stats 2010 ch 658 § 5 (AB
2470), effective January 1, 2011; Stats 2024 ch
879 § 1 (SB 1120), effective January 1, 2025.