§ 1370.6. Coverage for approved clinical trials

(a) An individual or group health care service plan contract that is issued, amended, or renewed on or after January 1, 2020, shall not:

(1) Deny a qualified enrollee's participation in an approved clinical trial.

(2) Deny, limit, or impose additional conditions on the coverage of routine patient care costs for items and services furnished in connection with a qualified enrollee's participation in an approved clinical trial.

(3) Discriminate against an enrollee based on the qualified enrollee's participation in an approved clinical trial.

(b)(1) Subdivision (a) applies to:

(A) A qualified enrollee participating in an approved clinical trial conducted by a participating provider.

(B) A qualified enrollee participating in an approved clinical trial conducted by a nonparticipating provider, including a nonparticipating provider located outside this state, if the clinical trial is not offered or available through a participating provider.

(2) If one or more participating providers is conducting an approved clinical trial, a health care service plan may require a qualified enrollee to participate in the clinical trial through a participating provider if the participating provider accepts the enrollee as a clinical trial participant.

(3) A health care service plan may restrict coverage to an approved clinical trial in this state, unless the clinical trial is not offered or available through a participating provider in this state.

(c)(1) The payment rate for routine patient care costs provided by a nonparticipating provider under a contract that is issued, amended, or renewed on or after January 1, 2020, shall be the negotiated rate the health care service plan would otherwise pay a participating provider for the same services, less applicable cost sharing.

(2) Cost sharing for routine patient care costs shall be the same as that

applied to the same services not delivered in a clinical trial, except that the in-network cost sharing and out-of-pocket maximum shall apply if the clinical trial is not offered or available through a participating provider.

(3) This section does not limit or modify any existing requirements under this chapter or prevent application of cost-sharing provisions in a contract, except as provided in paragraph (2).

(d) For purposes of this section:

(1) "Approved clinical trial" means a phase I, phase II, phase III, or phase IV clinical trial conducted in relation to the prevention, detection, or treatment of cancer or another life-threatening disease or condition that meets at least one of the following:

(A) The study or investigation is approved or funded, which may include funding through in-kind donations, by one or more of the following:

(i) The National Institutes of Health.

(ii) The federal Centers for Disease Control and Prevention.

(iii) The Agency for Healthcare Research and Quality.

(iv) The federal Centers for Medicare and Medicaid Services.

(v) A cooperative group or center of any of the entities described in clauses (i) to (iv), inclusive, the Department of Defense, or the United States Department of Veterans Affairs.

(vi) A qualified nongovernmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

(vii) One of the following departments, if the study or investigation has been reviewed and approved through a system of peer review that the Secretary of the United States Department of Health and Human Services determines is comparable to the system of peer review used by the National Institutes of Health and ensures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review:

(I) The United States Department of Veterans Affairs.

(II) The United States Department of Defense.

(III) The United States Department of Energy.

(B) The study or investigation is conducted under an investigational new drug application reviewed by the United States Food and Drug Administration.

(C) The study or investigation is a drug trial that is exempt from an investigational new drug application reviewed by the United States Food and Drug Administration.

(2) "Life-threatening disease or condition" means a disease or condition from which the likelihood of death is probable, unless the course of the disease or condition is interrupted.

(3) "Qualified enrollee" means an enrollee who meets both of the following conditions:

(A) The enrollee is eligible to participate in an approved clinical trial, according to the clinical trial protocol, for the treatment of cancer or another life-threatening disease or condition.

(B) Either of the following applies:

(i) The referring health care professional is a participating provider and has concluded that the enrollee's participation in the clinical trial

would be appropriate because the enrollee meets the conditions of subparagraph (A).

(ii) The enrollee provides medical and scientific information establishing that the enrollee's participation in the clinical trial would be appropriate because the enrollee meets the conditions of subparagraph (A).

(4) "Routine patient care costs" include drugs, items, devices, and services provided consistent with coverage under the contract for an enrollee who is not enrolled in an approved clinical trial, including the following:

(A) Drugs, items, devices, and services typically covered absent a clinical trial.

(B) Drugs, items, devices, and services required solely for the provision of an investigational drug, item, device, or service.

(C) Drugs, items, devices, and services required for the clinically appropriate monitoring of the investigational drug, item, device, or service.

(D) Drugs, items, devices, and services provided for the prevention of complications arising from the provision of the investigational drug, item, device, or service.

(E) Drugs, items, devices, and services needed for the reasonable and necessary care arising from the provision of the investigational drug, item, device, or service, including diagnosis and treatment of complications.

(5) "Routine patient care costs" does not include the following:

(A) The investigational drug, item, device, or service itself.

(B) Drugs, items, devices, and services provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the enrollee.

(C) Drugs, items, devices, and services specifically excluded from coverage in the contract, except for drugs, items, devices, and services required to be covered pursuant to this section or other applicable law.

(D) Drugs, items, devices, and services customarily provided free of charge to a clinical trial participant by the research sponsor.

(e) This section shall not be construed to limit coverage provided by a health care service plan contract with respect to clinical trials.

(f) The provision of services required by this section shall not, in itself, give rise to liability on the part of the health care service plan.

(g) This section does not apply to a specialized health care service plan contract.

(h) This section does not limit, prohibit, or modify an enrollee's rights to the independent review process available under Section 1370.4 or to the Independent Medical Review System available under Article 5.55 (commencing with Section 1374.30).

HISTORY:

Added Stats 2019 ch 482 § 2 (SB 583), effective January 1, 2020.

§ 1371. Reimbursement of claims; Contested claims [Effective until January 1, 2026; Repealed effective January 1, 2026]

(a)(1) A health care service plan, including a specialized health care service

plan, shall reimburse claims or a portion of a claim, whether in state or out of state, as soon as practicable, but no later than 30 working days after receipt of the claim by the health care service plan, or if the health care service plan is a health maintenance organization, 45 working days after receipt of the claim by the health care service plan, unless the claim or portion thereof is contested by the plan, in which case the claimant shall be notified, in writing, that the claim is contested or denied, within 30 working days after receipt of the claim by the health care service plan, or if the health care service plan is a health maintenance organization, 45 working days after receipt of the claim by the health care service plan. The notice that a claim is being contested shall identify the portion of the claim that is contested and the specific reasons for contesting the claim.

(2) If an uncontested claim is not reimbursed by delivery to the claimant's address of record within the respective 30 or 45 working days after receipt, interest shall accrue at the rate of 15 percent per annum beginning with the first calendar day after the 30- or 45-working-day period. A health care service plan shall automatically include in its payment of the claim all interest that has accrued pursuant to this section without requiring the claimant to submit a request for the interest amount. A plan failing to comply with this requirement shall pay the claimant a ten dollar ($10) fee.

(3) For the purposes of this section, a claim, or portion thereof, is reasonably contested if the plan has not received the completed claim and all information necessary to determine payer liability for the claim, or has not been granted reasonable access to information concerning provider services. Information necessary to determine payer liability for the claim includes, but is not limited to, reports of investigations concerning fraud and misrepresentation, and necessary consents, releases, and assignments, a claim on appeal, or other information necessary for the plan to determine the medical necessity for the health care services provided.

(4) If a claim or portion thereof is contested on the basis that the plan has not received all information necessary to determine payer liability for the claim or portion thereof and notice has been provided pursuant to this section, the plan shall have 30 working days or, if the health care service plan is a health maintenance organization, 45 working days after receipt of this additional information to complete reconsideration of the claim. If a plan has received all of the information necessary to determine payer liability for a contested claim and has not reimbursed a claim it has determined to be payable within 30 working days of the receipt of that information, or if the plan is a health maintenance organization, within 45 working days of receipt of that information, interest shall accrue and be payable at a rate of 15 percent per annum beginning with the first calendar day after the 30- or 45-working-day period.

(b) Notwithstanding any other law, a specialized health care service plan that undertakes solely to arrange for the provision of vision care services may use a statistically reliable method to investigate suspected fraud and to recover overpayments made as a result of fraud only if the specialized health care service plan complies with this subdivision.

(1) A specialized health care service plan's statistically reliable method, and how the specialized health care service plan intends to utilize that

method to determine recovery of overpayments made as a result of fraud, shall be submitted to, and approved by, the department as elements of the specialized health care service plan's antifraud plan established and approved pursuant to Section 1348. The specialized health care service plan's utilization of a statistically reliable method shall help protect and promote the interests of enrollees and shall help ensure a stable health care delivery system. The statistically reliable method shall be consistent with direction provided by the International Standards for the Professional Practice of Internal Auditing and the guidance provided by the International Professional Practices Framework guide, which are both produced by the Institute of Internal Auditors.

(2) Pursuant to its antifraud plan established and approved pursuant to Section 1348, a specialized health care service plan shall provide a written notice of suspected fraud to a provider that includes, at a minimum, all of the following:

(A) A clear description of the specialized health care service plan's statistically reliable methodology. The description shall include information that ensures that the sample size used to calculate the repayment amount is consistent with the professional guidance provided in the 2009 edition of the American Institute of Certified Public Accountants' Audit Sampling Considerations of Circular A-133 Compliance Audits.

(B) A clear description of the universe of claims from which the statistical random sample was drawn and, if different, the universe of claims upon which the statistical analysis was applied to generate the recovery amount.

(C) A clear explanation of how the specialized health care service plan's statistically reliable methodology was utilized in the specialized health care service plan's findings of suspected fraud.

(D) Notice that a provider may dispute the specialized health care service plan's findings within 45 working days from the date of receipt of the notice of suspected fraud.

(E) The following information for each of the claims in the statistical sample that was utilized in the specialized health care service plan's findings:

(i) The claim number.

(ii) The name of the patient.

(iii) The date of service.

(iv) The date of payment.

(v) A clear explanation of the basis upon which the specialized health care service plan suspects the claim is fraudulent.

(3) A specialized health care service plan that undertakes solely to arrange for the provision of vision care services may use a statistically reliable method to recover overpayments made as a result of suspected fraud only if the universe of claims upon which the statistical analysis is performed consists only of those claims made between 365 days from the date of payment of the earliest in time claim and the date of payment of the latest in time claim. Notice shall be mailed to the provider no later than 60 days following the date of payment of the latest in time claim.

(4) If the provider contests the specialized health care service plan's notice of suspected fraud, the provider, within 45 working days of the date of receipt

of the notice of suspected fraud, shall send written notice to the specialized health care service plan stating the basis upon which the provider believes that the claims are not fraudulent. The specialized health care service plan shall receive and process this contested notice of suspected fraud as a provider dispute pursuant to subdivision (a) of this section, paragraph (1) of subdivision (h) of Section 1367, and the regulations promulgated thereunder.

(5) A specialized health care service plan may offset the amount the specialized health care service plan disclosed as overpaid to the provider in an uncontested notice of suspected fraud against the provider's current claim submissions only if all of the following requirements are met:

(A) The provider fails to reimburse the specialized health care service plan within 45 working days from the date of receipt by the provider of the notice of suspected fraud.

(B) The specialized health care service plan sends written notice to the provider no less than 10 working days prior to withholding current claim payments in which the specialized health care service plan, at a minimum, states its intent to withhold current claim payments and identifies the claim payments that the specialized health care service plan intends to withhold.

(C) The withheld claim payments do not exceed the amount asserted by the specialized health care service plan to be owed to the specialized health care service plan in its notice of suspected fraud.

(6) This section does not limit or remove a specialized health care service plan's obligation to comply with its antifraud plan established pursuant to Section 1348, or to limit or remove the specialized health care service plan's obligation to comply with the requirements for claims subject to subdivision (a).

(7) This subdivision does not limit or remove a specialized health care service plan's ability to recover overpayments as long as recovery is consistent with applicable law, including subdivision (a) and the regulations promulgated thereunder.

(8) This subdivision does not apply to claims submitted by a physician and surgeon for medical or surgical services that are outside the scope of practice of an optometrist pursuant to the Optometry Practice Act (Chapter 7 (commencing with Section 3000) of Division 2 of the Business and Professions Code).

(c) The obligation of a plan to comply with this section shall not be deemed to be waived when the plan requires its medical groups, independent practice associations, or other contracting entities to pay claims for covered services.

(d) This section shall remain in effect only until January 1, 2026, and as of that date is repealed.

HISTORY:

Added Stats 1986 ch 957 § 1. Amended Stats 1989 ch 968 § 1; Stats 1992 ch 747 § 1 (AB 2656), ch 1357 § 1 (SB 382); Stats 1994 ch 614 § 3 (SB 1832); Stats 1996 ch 711 § 1 (SB 1478); Stats 2000 ch 825 § 3 (SB 1177), ch 827 § 3 (AB 1455); Stats 2009 ch 140 § 98 (AB 1164), effective January 1, 2010; Stats 2018 ch 525 § 1 (AB 1092), effective January 1, 2019; Stats 2019 ch 113 § 4 (AB 1802), effective January 1, 2020; Stats 2024 ch 763 § 1 (AB 3275), effective January 1, 2025, repealed January 1, 2026.

§ 1371. Timely reimbursement of claims for emergency services [Op- erative January 1, 2026]

(a)(1) A health care service plan, including a specialized health care service plan, shall reimburse a complete claim or portion thereof, whether in state or out of state, as soon as practicable, but no later than 30 calendar days after receipt of the claim by the health care service plan. If a claim or portion thereof does not meet the criteria for a complete claim or the criteria for coverage under the plan contract, the claimant shall be notified, in writing, that the claim or portion thereof is contested or denied, as soon as practicable, but no later than 30 calendar days after receipt of the claim by the health care service plan.

(2) The notice that a claim or portion thereof, is contested shall identify the portion of the claim that is contested, by procedure or revenue code, and the specific information needed from the provider to reconsider the claim, including any defect or impropriety or additional information needed to adjudicate the claim.

(3) The notice that a claim or portion thereof, is denied shall identify the portion of the claim that is denied, by procedure or revenue code, and the specific reasons for the denial including any defect or impropriety.

(4) If a complete claim is not reimbursed by delivery to the claimant's address of record within 30 calendar days after receipt, interest shall accrue at a rate of 15 percent per annum beginning with the first calendar day after the 30-calendar-day period. A health care service plan shall automatically include in its payment of the claim all interest that has accrued pursuant to this section without requiring the claimant to submit a request for the interest amount. A plan failing to comply with this requirement shall pay the claimant a fee of the greater of an additional fifteen dollars ($15) or 10 percent of the accrued interest.

(5) For the purposes of this section, a claim, or portion thereof, is reasonably contested if the plan has not received the completed claim and all information necessary to determine payer liability for the claim, or has not been granted reasonable access to information concerning provider services. Information necessary to determine payer liability for the claim includes, but is not limited to, reports of investigations concerning fraud and misrepresentation, and necessary consents, releases, and assignments, a claim on appeal, or other information necessary for the plan to determine the medical necessity for the health care services provided. A plan may not contest a claim that is consistent with the procedure or revenue codes and services approved by prior authorization with appropriate documentation included on the claim.

(6) If a claim or portion thereof is contested on the basis that the plan has not received all information necessary to determine payer liability for the claim or portion thereof and notice has been provided pursuant to this section, the plan shall have 30 calendar days after receipt of this additional information to complete reconsideration of the claim. If a plan has received all of the information necessary to determine payer liability for a contested claim and has not reimbursed a claim it has determined to be payable within 30 calendar days of the receipt of that information, interest shall accrue and

be payable at a rate of 15 percent per annum beginning with the first calendar day after the 30-calendar-day period.

(b) Notwithstanding any other law, a specialized health care service plan that undertakes solely to arrange for the provision of vision care services may use a statistically reliable method to investigate suspected fraud and to recover overpayments made as a result of fraud only if the specialized health care service plan complies with this subdivision.

(1) A specialized health care service plan's statistically reliable method, and how the specialized health care service plan intends to utilize that method to determine recovery of overpayments made as a result of fraud, shall be submitted to, and approved by, the department as elements of the specialized health care service plan's antifraud plan established and approved pursuant to Section 1348. The specialized health care service plan's utilization of a statistically reliable method shall help protect and promote the interests of enrollees and shall help ensure a stable health care delivery system. The statistically reliable method shall be consistent with direction provided by the International Standards for the Professional Practice of Internal Auditing and the guidance provided by the International Professional Practices Framework guide, which are both produced by the Institute of Internal Auditors.

(2) Pursuant to its antifraud plan established and approved pursuant to Section 1348, a specialized health care service plan shall provide a written notice of suspected fraud to a provider that includes, at a minimum, all of the following:

(A) A clear description of the specialized health care service plan's statistically reliable methodology. The description shall include information that ensures that the sample size used to calculate the repayment amount is consistent with the professional guidance provided in the 2009 edition of the American Institute of Certified Public Accountants' Audit Sampling Considerations of Circular A-133 Compliance Audits.

(B) A clear description of the universe of claims from which the statistical random sample was drawn and, if different, the universe of claims upon which the statistical analysis was applied to generate the recovery amount.

(C) A clear explanation of how the specialized health care service plan's statistically reliable methodology was utilized in the specialized health care service plan's findings of suspected fraud.

(D) Notice that a provider may dispute the specialized health care service plan's findings within 45 working days from the date of receipt of the notice of suspected fraud.

(E) The following information for each of the claims in the statistical sample that was utilized in the specialized health care service plan's findings:

(i) The claim number.

(ii) The name of the patient.

(iii) The date of service.

(iv) The date of payment.

(v) A clear explanation of the basis upon which the specialized health care service plan suspects the claim is fraudulent.

(3) A specialized health care service plan that undertakes solely to arrange for the provision of vision care services may use a statistically reliable method to recover overpayments made as a result of suspected fraud only if the universe of claims upon which the statistical analysis is performed consists only of those claims made between 365 days from the date of payment of the earliest in time claim and the date of payment of the latest in time claim. Notice shall be mailed to the provider no later than 60 days following the date of payment of the latest in time claim.

(4) If the provider contests the specialized health care service plan's notice of suspected fraud, the provider, within 45 working days of the date of receipt of the notice of suspected fraud, shall send written notice to the specialized health care service plan stating the basis upon which the provider believes that the claims are not fraudulent. The specialized health care service plan shall receive and process this contested notice of suspected fraud as a provider dispute pursuant to subdivision (a) of this section, paragraph (1) of subdivision (h) of Section 1367, and the regulations promulgated thereunder.

(5) A specialized health care service plan may offset the amount the specialized health care service plan disclosed as overpaid to the provider in an uncontested notice of suspected fraud against the provider's current claim submissions only if all of the following requirements are met:

(A) The provider fails to reimburse the specialized health care service plan within 45 working days from the date of receipt by the provider of the notice of suspected fraud.

(B) The specialized health care service plan sends written notice to the provider no less than 10 working days prior to withholding current claim payments in which the specialized health care service plan, at a minimum, states its intent to withhold current claim payments and identifies the claim payments that the specialized health care service plan intends to withhold.

(C) The withheld claim payments do not exceed the amount asserted by the specialized health care service plan to be owed to the specialized health care service plan in its notice of suspected fraud.

(6) This section does not limit or remove a specialized health care service plan's obligation to comply with its antifraud plan established pursuant to Section 1348, or to limit or remove the specialized health care service plan's obligation to comply with the requirements for claims subject to subdivision (a).

(7) This subdivision does not limit or remove a specialized health care service plan's ability to recover overpayments as long as recovery is consistent with applicable law, including subdivision (a) and the regulations promulgated thereunder.

(8) This subdivision does not apply to claims submitted by a physician and surgeon for medical or surgical services that are outside the scope of practice of an optometrist pursuant to the Optometry Practice Act (Chapter 7 (commencing with Section 3000) of Division 2 of the Business and Professions Code).

(c) The obligation of a plan to comply with this section shall not be deemed to be waived when the plan requires its medical groups, independent practice associations, or other contracting entities to pay claims for covered services.

(d) The department may issue compliance guidance and amend regulations for consistency with this section. The guidance and amendments shall not be subject to the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) until December 31, 2027.

(e) This section shall become operative on January 1, 2026.

HISTORY:

Added Stats 2024 ch 763 § 2 (AB 3275), effective January 1, 2025, operative January 1, 2026.