described in §148.310. A State must include sufficient documentation of the losses incurred in the operation of the qualified high risk pool in the period for when it is applying.

(d) *Review criteria.* If the review team determines that a State meets the eligibility requirements described in §148.310, the review team will use the following additional criteria in reviewing the applications:

(1) *Documentation of expenses incurred during operation of the qualified high risk pool.* The losses and expenses incurred in the operation of a State's pool are sufficiently documented.

(2) *Funding mechanism.* The State has outlined funding sources, such as assessments and State general revenues, which can cover the projected costs and are reasonably designed to ensure continued funding of losses a State incurs in connection with the operation of the qualified high risk pool after each fiscal year for which it is applying for grant funds.

[68 FR 23414, May 2, 2003, as amended at 72 FR 41238, July 27, 2007; 73 FR 22286, Apr. 25, 2008]

§148.320 Grant awards.

(a) *Notification and award letter.* (1) Each State applicant will be notified in writing of CMS's decision on its application.

(2) If the State applicant is awarded a grant, the award letter will contain the following terms and conditions:

(i) All funds awarded to the grantee under this program must be used exclusively for the operation of a qualified high risk pool that meets the eligibility requirements for this program.

(ii) The grantee must keep sufficient records of the grant expenditures for audit purposes (see part 92 of this title).

(iii) The grantee will be required to submit quarterly progress and financial reports under part 92 of this title and in accordance with section 2745(f) of the Public Health Service Act, requiring the Secretary to make an annual report to Congress that includes information on the use of these grant funds by States.

(b) *Grantees letter of acceptance.* Grantees must submit a letter of acceptance to CMS' Acquisition and Grants Group within 30 days of the date of the award agreeing to the terms and conditions of the award letter.

[68 FR 23414, May 2, 2003, as amended at 72 FR 41238, July 27, 2007; 73 FR 22286, Apr. 25, 2008]

PART 149—SURPRISE BILLING AND TRANSPARENCY REQUIREMENTS

Subpart A—General Provisions

Sec.

Subpart B—Protections against Balance Billing for the Group and Individual Health Insurance Markets

Subpart C [Reserved]

Subpart D—Additional Patient Protections

Subpart E—Health Care Provider, Health Care Facility, and Air Ambulance Service Provider Requirements

Subpart F—Independent Dispute Resolution Process

AUTHORITY: 42 U.S.C. 300gg–92 and 300gg–111 through 300gg–139, as amended.

SOURCE: 86 FR 36970, July 13, 2021, unless otherwise noted.

Subpart A—General Provisions

§ 149.10 Basis and scope.

(a) *Basis.* This part implements parts D and E of title XXVII of the PHS Act.

(b) *Scope.* This part establishes standards for group health plans, health insurance issuers offering group or individual health insurance coverage, health care providers and facilities, and providers of air ambulance services with respect to surprise medical bills, transparency in health care coverage, and additional patient protections. This part also establishes an independent dispute resolution process, and standards for certifying independent dispute resolution entities. This part also establishes a Patient-Provider Dispute Resolution Process and standards for certifying Selected Dispute Resolution entities.

[86 FR 36970, July 13, 2021, as amended at 86 FR 56124, Oct. 7, 2021]

§ 149.20 Applicability.

(a) *In general.* (1) The requirements in subparts B, D, and H of this part apply to group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans as defined in § 147.140 of this subchapter), except as specified in paragraph (b) of this section.

(2) The requirements in subpart E of this part apply to health care providers, health care facilities, and providers of air ambulance services.

(3) The requirements in subpart F of this part apply to certified IDR entities, health care providers, health care facilities, and providers of air ambulance services and group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans as defined in § 147.140 of this subchapter) except as specified in paragraph (b) of this section.

(4) The requirements in subpart G of this part apply to Selected Dispute Resolution Entities, health care providers, providers of air ambulance services, health care facilities and uninsured (or self-pay) individuals, as defined in subpart G.

(b) *Exceptions.* The requirements in subparts B, D, E, F, and H of this part do not apply to the following:

(1) Excepted benefits as described in §§ 146.145 and 148.220 of this subchapter.

(2) Short-term, limited-duration insurance as defined in § 144.103 of this subchapter.

(3) Health reimbursement arrangements or other account-based group health plans as described in § 147.126(d) of this subchapter.

[86 FR 36970, July 13, 2021, as amended at 86 FR 56124, Oct. 7, 2021; 86 FR 66702, Nov. 23, 2021]

§ 149.30 Definitions.

The definitions in part 144 of this subchapter apply to this part, unless otherwise specified. In addition, for purposes of this part, the following definitions apply:

Air ambulance service means medical transport by a rotary wing air ambulance, as defined in 42 CFR 414.605, or fixed wing air ambulance, as defined in 42 CFR 414.605, for patients.

Cost sharing means the amount a participant, beneficiary, or enrollee is responsible for paying for a covered item or service under the terms of the group health plan or health insurance coverage. Cost sharing generally includes copayments, coinsurance, and amounts paid towards deductibles, but does not

include amounts paid towards premiums, balance billing by out-of-network providers, or the cost of items or services that are not covered under a group health plan or health insurance coverage.

Emergency department of a hospital includes a hospital outpatient department that provides emergency services.

Emergency medical condition has the meaning given the term in §149.110(c)(1).

Emergency services has the meaning given the term in §149.110(c)(2).

Health care facility, with respect to a group health plan or group or individual health insurance coverage, in the context of non-emergency services, is each of the following:

(1) A hospital (as defined in section 1861(e) of the Social Security Act);

(2) A hospital outpatient department;

(3) A critical access hospital (as defined in section 1861(mm)(1) of the Social Security Act); and

(4) An ambulatory surgical center described in section 1833(i)(1)(A) of the Social Security Act.

Independent freestanding emergency department means a health care facility (not limited to those described in the definition of health care facility with respect to non-emergency services) that—

(1) Is geographically separate and distinct and licensed separately from a hospital under applicable State law; and

(2) Provides any emergency services as described in §149.110(c)(2)(i).

Nonparticipating emergency facility means an emergency department of a hospital, or an independent freestanding emergency department (or a hospital, with respect to services that pursuant to §149.110(c)(2)(ii) are included as emergency services), that does not have a contractual relationship directly or indirectly with a group health plan or group or individual health insurance coverage offered by a health insurance issuer, with respect to the furnishing of an item or service under the plan or coverage, respectively.

Nonparticipating provider means any physician or other health care provider who does not have a contractual relationship directly or indirectly with a group health plan or group or individual health insurance coverage offered by a health insurance issuer, with respect to the furnishing of an item or service under the plan or coverage, respectively.

Notice of denial of payment means, with respect to an item or service for which benefits subject to the protections of §§149.110 through 149.130 are provided or covered, a written notice from the plan or issuer to the health care provider, facility, or provider of air ambulance services, as applicable, that payment for such item or service will not be made by the plan or coverage and which explains the reason for denial. The term notice of denial of payment does not include a notice of benefit denial due to an adverse benefit determination as defined in 29 CFR 2560.503–1.

Out-of-network rate means, with respect to an item or service furnished by a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services—

(1) Subject to paragraph (3) of this definition, in a State that has in effect a specified State law, the amount determined in accordance with such law;

(2) Subject to paragraph (3) of this definition, in a State that does not have in effect a specified State law—

(i) Subject to paragraph (2)(ii) of this definition, if the nonparticipating provider or nonparticipating emergency facility and the plan or issuer agree on an amount of payment (including if the amount agreed upon is the initial payment sent by the plan or issuer under 26 CFR 54.9816–4T(b)(3)(iv)(A), 54.9816–5T(c)(3), or 54.9817–1T(b)(4)(i); 29 CFR 2590.716–4(b)(3)(iv)(A), 2590.716–5(c)(3), or 2590.717–1(b)(4)(i); or §149.110(b)(3)(iv)(A), §149.120(c)(3), or §149.130(b)(4)(i), as applicable, or is agreed on through negotiations with respect to such item or service), such agreed on amount; or

(ii) If the nonparticipating provider or nonparticipating emergency facility and the plan or issuer enter into the independent dispute resolution (IDR) process under section 9816(c) or 9817(b) of the Internal Revenue Code, section 716(c) or 717(b) of ERISA, or section 2799A–1(c) or 2799A–2(b) of the PHS Act,

as applicable, and do not agree before the date on which a certified IDR entity makes a determination with respect to such item or service under such subsection, the amount of such determination; or

(3) In a State that has an All-Payer Model Agreement under section 1115A of the Social Security Act that applies with respect to the plan or issuer; the nonparticipating provider or nonparticipating emergency facility; and the item or service, the amount that the State approves under the All-Payer Model Agreement for the item or service.

Participating emergency facility means any emergency department of a hospital, or an independent freestanding emergency department (or a hospital, with respect to services that pursuant to §149.110(c)(2)(ii) are included as emergency services), that has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group or individual health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee under the plan or coverage, respectively. A single case agreement between an emergency facility and a plan or issuer that is used to address unique situations in which a participant, beneficiary, or enrollee requires services that typically occur out-of-network constitutes a contractual relationship for purposes of this definition, and is limited to the parties to the agreement.

Participating health care facility means any health care facility described in this section that has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group or individual health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee under the plan or coverage, respectively. A single case agreement between a health care facility and a plan or issuer that is used to address unique situations in which a participant, beneficiary, or enrollee requires services that typically occur out-of-network constitutes a contractual relationship for purposes of this definition, and is limited to the parties to the agreement.

Participating provider means any physician or other health care provider who has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group or individual health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee under the plan or coverage, respectively.

Physician or health care provider means a physician or other health care provider who is acting within the scope of practice of that provider's license or certification under applicable State law, but does not include a provider of air ambulance services.

Provider of air ambulance services means an entity that is licensed under applicable State and Federal law to provide air ambulance services.

Same or similar item or service has the meaning given the term in §149.140(a)(13).

Service code has the meaning given the term in §149.140(a)(14).

Qualifying payment amount has the meaning given the term in §149.140(a)(16).

Recognized amount means, with respect to an item or service furnished by a nonparticipating provider or nonparticipating emergency facility—

(1) Subject to paragraph (3) of this definition, in a State that has in effect a specified State law, the amount determined in accordance with such law.

(2) Subject to paragraph (3) of this definition, in a State that does not have in effect a specified State law, the lesser of—

(i) The amount that is the qualifying payment amount (as determined in accordance with §149.140); or

(ii) The amount billed by the provider or facility.

(3) In a State that has an All-Payer Model Agreement under section 1115A of the Social Security Act that applies with respect to the plan or issuer; the nonparticipating provider or nonparticipating emergency facility; and the item or service, the amount that the State approves under the All-Payer

Model Agreement for the item or service.

Specified State law means a State law that provides for a method for determining the total amount payable under a group health plan or group or individual health insurance coverage offered by a health insurance issuer to the extent such State law applies for an item or service furnished by a nonparticipating provider or nonparticipating emergency facility (including where it applies because the State has allowed a plan that is not otherwise subject to applicable State law an opportunity to opt in, subject to section 514 of the Employee Retirement Income Security Act of 1974). A group health plan that opts in to such a specified State law must do so for all items and services to which the specified State law applies and in a manner determined by the applicable State authority, and must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted into the specified State law, identify the relevant State (or States), and include a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified State law.

State means each of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

Treating provider is a physician or health care provider who has evaluated the individual.

Visit, with respect to items and services furnished to an individual at a health care facility, includes, in addition to items and services furnished by a provider at the facility, equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services, regardless of whether the provider furnishing such items or services is at the facility.

Subpart B—Protections Against Balance Billing for the Group and Individual Health Insurance Markets

§ 149.110 Preventing surprise medical bills for emergency services.

(a) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department, the plan or issuer must cover emergency services, as defined in paragraph (c)(2) of this section, and this coverage must be provided in accordance with paragraph (b) of this section.

(b) *Coverage requirements.* A plan or issuer described in paragraph (a) of this section must provide coverage for emergency services in the following manner—

(1) Without the need for any prior authorization determination, even if the services are provided on an out-of-network basis.

(2) Without regard to whether the health care provider furnishing the emergency services is a participating provider or a participating emergency facility, as applicable, with respect to the services.

(3) If the emergency services are provided by a nonparticipating provider or a nonparticipating emergency facility—

(i) Without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from participating providers and participating emergency facilities.

(ii) Without imposing cost-sharing requirements that are greater than the requirements that would apply if the services were provided by a participating provider or a participating emergency facility.

(iii) By calculating the cost-sharing requirement as if the total amount that would have been charged for the services by such participating provider or participating emergency facility

were equal to the recognized amount for such services.

(iv) The plan or issuer—

(A) Not later than 30 calendar days after the bill for the services is transmitted by the provider or facility (or, in cases where the recognized amount is determined by a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement), determines whether the services are covered under the plan or coverage and, if the services are covered, sends to the provider or facility, as applicable, an initial payment or a notice of denial of payment. For purposes of this paragraph (b)(3)(iv)(A), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the services.

(B) Pays a total plan or coverage payment directly to the nonparticipating provider or nonparticipating facility that is equal to the amount by which the out-of-network rate for the services exceeds the cost-sharing amount for the services (as determined in accordance with paragraphs (b)(3)(ii) and (iii) of this section), less any initial payment amount made under paragraph (b)(3)(iv)(A) of this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section 2799A–1(c)(6) of the PHS Act, or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(v) By counting any cost-sharing payments made by the participant, beneficiary, or enrollee with respect to the emergency services toward any in-network deductible or in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable) applied under the plan or coverage (and the in-network deductible and in-network out-of-pocket maximums must be applied) in the same manner as if the cost-sharing payments were made with respect to emergency services furnished by a participating provider or a participating emergency facility.

(4) Without limiting what constitutes an emergency medical condition (as defined in paragraph (c)(1) of this section) solely on the basis of diagnosis codes.

(5) Without regard to any other term or condition of the coverage, other than—

(i) The exclusion or coordination of benefits (to the extent not inconsistent with benefits for an emergency medical condition, as defined in paragraph (c)(1) of this section).

(ii) An affiliation or waiting period (each as defined in §144.103 of this subchapter).

(iii) Applicable cost sharing.

(c) *Definitions.* In this section—

(1) *Emergency medical condition* means a medical condition, including a mental health condition or substance use disorder, manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(2) *Emergency services* means, with respect to an emergency medical condition—

(i) *In general.* (A) An appropriate medical screening examination (as required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) or as would be required under such section if such section applied to an independent freestanding emergency department) that is within the capability of the emergency department of a hospital or of an independent freestanding emergency department, as applicable, including ancillary services routinely available to the emergency department

to evaluate such emergency medical condition; and

(B) Within the capabilities of the staff and facilities available at the hospital or the independent freestanding emergency department, as applicable, such further medical examination and treatment as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd), or as would be required under such section if such section applied to an independent freestanding emergency department, to stabilize the patient (regardless of the department of the hospital in which such further examination or treatment is furnished).

(ii) *Inclusion of additional services.* (A) Subject to paragraph (c)(2)(ii)(B) of this section, items and services—

(*1*) For which benefits are provided or covered under the plan or coverage; and

(*2*) That are furnished by a nonparticipating provider or nonparticipating emergency facility (regardless of the department of the hospital in which such items or services are furnished) after the participant, beneficiary, or enrollee is stabilized and as part of outpatient observation or an inpatient or outpatient stay with respect to the visit in which the services described in paragraph (c)(2)(i) of this section are furnished.

(B) Items and services described in paragraph (c)(2)(ii)(A) of this section are not included as emergency services if all of the conditions in §149.410(b) are met.

(3) *To stabilize*, with respect to an emergency medical condition, has the meaning given such term in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(d) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

§149.120 Preventing surprise medical bills for non-emergency services performed by nonparticipating providers at certain participating facilities.

(a) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers any benefits with respect to items and services described in paragraph (b) of this section, the plan or issuer must cover the items and services when furnished by a nonparticipating provider in accordance with paragraph (c) of this section.

(b) *Items and services described.* The items and services described in this paragraph (b) are items and services (other than emergency services) furnished to a participant, beneficiary, or enrollee by a nonparticipating provider with respect to a visit at a participating health care facility, unless the provider has satisfied the notice and consent criteria of §149.420(c) through (i) with respect to such items and services.

(c) *Coverage requirements.* In the case of items and services described in paragraph (b) of this section, the plan or issuer—

(1) Must not impose a cost-sharing requirement for the items and services that is greater than the cost-sharing requirement that would apply if the items or services had been furnished by a participating provider.

(2) Must calculate the cost-sharing requirements as if the total amount that would have been charged for the items and services by such participating provider were equal to the recognized amount for the items and services.

(3) Not later than 30 calendar days after the bill for the items or services is transmitted by the provider (or in cases where the recognized amount is determined by a specified State law or All-Payer Model Agreement, such other timeframe as specified under the State law or All-Payer Model Agreement), must determine whether the items and services are covered under the plan or coverage and, if the items and services are covered, send to the provider an initial payment or a notice of denial of payment. For purposes of this paragraph (c)(3), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the items or services.

(4) Must pay a total plan or coverage payment directly to the nonparticipating provider that is equal to the amount by which the out-of-network rate for the items and services involved

exceeds the cost-sharing amount for the items and services (as determined in accordance with paragraphs (c)(1) and (2) of this section), less any initial payment amount made under paragraph (c)(3) of this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section 2799A–1(c)(6) of the PHS Act, or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(5) Must count any cost-sharing payments made by the participant, beneficiary, or enrollee toward any in-network deductible and in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable) applied under the plan or coverage (and the in-network deductible and out-of-pocket maximums must be applied) in the same manner as if such cost-sharing payments were made with respect to items and services furnished by a participating provider.

(d) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

§ 149.130 Preventing surprise medical bills for air ambulance services.

(a) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers any benefits for air ambulance services, the plan or issuer must cover such services from a nonparticipating provider of air ambulance services in accordance with paragraph (b) of this section.

(b) *Coverage requirements.* A plan or issuer described in paragraph (a) of this section must provide coverage of air ambulance services in the following manner—

(1) The cost-sharing requirements with respect to the services must be the same requirements that would apply if the services were provided by a participating provider of air ambulance services.

(2) The cost-sharing requirement must be calculated as if the total amount that would have been charged for the services by a participating provider of air ambulance services were equal to the lesser of the qualifying payment amount (as determined in accordance with §149.140) or the billed amount for the services.

(3) The cost-sharing amounts must be counted towards any in-network deductible and in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable) applied under the plan or coverage (and the in-network deductible and out-of-pocket maximums must be applied) in the same manner as if the cost-sharing payments were made with respect to services furnished by a participating provider of air ambulance services.

(4) The plan or issuer must—

(i) Not later than 30 calendar days after the bill for the services is transmitted by the provider of air ambulance services, determine whether the services are covered under the plan or coverage and, if the services are covered, send to the provider an initial payment or a notice of denial of payment. For purposes of this paragraph (b)(4)(i), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the services.

(ii) Pay a total plan or coverage payment directly to the nonparticipating provider furnishing such air ambulance services that is equal to the amount by which the out-of-network rate for the services exceeds the cost-sharing amount for the services (as determined in accordance with paragraphs (b)(1) and (2) of this section), less any initial payment amount made under paragraph (b)(4)(i) of this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section 2799A–2(b)(6) of the PHS Act, or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(c) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

§ 149.140 Methodology for calculating qualifying payment amount.

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Contracted rate* means the total amount (including cost sharing) that a group health plan or health insurance issuer has contractually agreed to pay a participating provider, facility, or provider of air ambulance services for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager. Solely for purposes of this definition, a single case agreement, letter of agreement, or other similar arrangement between a provider, facility, or air ambulance provider and a plan or issuer, used to supplement the network of the plan or coverage for a specific participant, beneficiary, or enrollee in unique circumstances, does not constitute a contract.

(2) *Derived amount* has the meaning given the term in §147.210 of this subchapter.

(3) *Eligible database* means—

(i) A State all-payer claims database; or

(ii) Any third-party database which—

(A) Is not affiliated with, or owned or controlled by, any health insurance issuer, or a health care provider, facility, or provider of air ambulance services (or any member of the same controlled group as, or under common control with, such an entity). For purposes of this paragraph (a)(3)(ii)(A), the term controlled group means a group of two or more persons that is treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended;

(B) Has sufficient information reflecting in-network amounts paid by group health plans or health insurance issuers offering group or individual health insurance coverage to providers, facilities, or providers of air ambulance services for relevant items and services furnished in the applicable geographic region; and

(C) Has the ability to distinguish amounts paid to participating providers and facilities by commercial payers, such as group health plans and health insurance issuers offering group or individual health insurance coverage, from all other claims data, such as amounts billed by nonparticipating providers or facilities and amounts paid by public payers, including the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of the Social Security Act (or a demonstration project under title XI of the Social Security Act), or the Children's Health Insurance Program under title XXI of the Social Security Act.

(4) *Facility of the same or similar facility type* means, with respect to emergency services, either—

(i) An emergency department of a hospital; or

(ii) An independent freestanding emergency department.

(5) *First coverage year* means, with respect to an item or service for which coverage is not offered in 2019 under a group health plan or group or individual health insurance coverage offered by a health insurance issuer, the first year after 2019 for which coverage for such item or service is offered under that plan or coverage.

(6) *First sufficient information year* means, with respect to a group health plan or group or individual health insurance coverage offered by a health insurance issuer—

(i) In the case of an item or service for which the plan or coverage does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in 2019, the first year after 2022 for which the plan or issuer has sufficient information to calculate the median of such contracted rates in the year immediately preceding that first year after 2022; and

(ii) In the case of a newly covered item or service, the first year after the first coverage year for such item or service with respect to such plan or coverage for which the plan or issuer has sufficient information to calculate

the median of the contracted rates described in paragraph (b) of this section in the year immediately preceding that first year.

(7) *Geographic region* means—

(i) For items and services other than air ambulance services—

(A) Subject to paragraphs (a)(7)(i)(B) and (C) of this section, one region for each metropolitan statistical area, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in a State, and one region consisting of all other portions of the State.

(B) If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region described in paragraph (a)(7)(i)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in the State, and one region consisting of all other portions of the State.

(C) If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region described in paragraph (a)(7)(i)(B) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau.

(ii) For air ambulance services—

(A) Subject to paragraph (a)(7)(ii)(B) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in the State, and one region consisting of all other portions of the State, determined based on the point of pick-up (as defined in 42 CFR 414.605).

(B) If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an air ambulance service provided in a geographic region described in paragraph (a)(7)(ii)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau, determined based on the point of pick-up (as defined in 42 CFR 414.605).

(8) *Insurance market* is, irrespective of the State, one of the following:

(i) The individual market (other than short-term, limited-duration insurance or individual health insurance coverage that consists solely of excepted benefits).

(ii) The large group market (other than coverage that consists solely of excepted benefits).

(iii) The small group market (other than coverage that consists solely of excepted benefits).

(iv) In the case of a self-insured group health plan, all self-insured group health plans (other than account-based plans, as defined in §147.126(d)(6)(i) of this subchapter, and plans that consist solely of excepted benefits) of the same plan sponsor, or at the option of the plan sponsor, all self-insured group health plans administered by the same entity (including a third-party administrator contracted by the plan), to the extent otherwise permitted by law, that is responsible for calculating the qualifying payment amount on behalf of the plan.

(9) *Modifiers* mean codes applied to the service code that provide a more specific description of the furnished item or service and that may adjust the payment rate or affect the processing or payment of the code billed.

(10) *Newly covered item or service* means an item or service for which coverage was not offered in 2019 under a group health plan or group or individual health insurance coverage offered by a health insurance issuer, but that is offered under the plan or coverage in a year after 2019.

(11) *New service code* means a service code that was created or substantially revised in a year after 2019.

(12) *Provider in the same or similar specialty* means the practice specialty of a

provider, as identified by the plan or issuer consistent with the plan's or issuer's usual business practice, except that, with respect to air ambulance services, all providers of air ambulance services are considered to be a single provider specialty.

(13) *Same or similar item or service* means a health care item or service billed under the same service code, or a comparable code under a different procedural code system.

(14) *Service code* means the code that describes an item or service using the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG) codes.

(15) *Sufficient information* means, for purposes of determining whether a group health plan or health insurance issuer offering group or individual health insurance coverage has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section—

(i) The plan or issuer has at least three contracted rates on January 31, 2019, to calculate the median of the contracted rates in accordance with paragraph (b) of this section; or

(ii) For an item or service furnished during a year after 2022 that is used to determine the first sufficient information year—

(A) The plan or issuer has at least three contracted rates on January 31 of the year immediately preceding that year to calculate the median of the contracted rates in accordance with paragraph (b) of this section; and

(B) The contracted rates under paragraph (a)(15)(ii)(A) of this section account (or are reasonably expected to account) for at least 25 percent of the total number of claims paid for that item or service for that year with respect to all plans of the sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) or all coverage offered by the issuer that are offered in the same insurance market.

(16) *Qualifying payment amount* means, with respect to a sponsor of a group health plan or health insurance issuer offering group or individual health insurance coverage, the amount calculated using the methodology described in paragraph (c) of this section.

(17) *Underlying fee schedule rate* means the rate for a covered item or service from a particular participating provider, providers, or facility that a group health plan or health insurance issuer uses to determine a participant's, beneficiary's, or enrollee's cost-sharing liability for the item or service, when that rate is different from the contracted rate.

(18) *Downcode* means the alteration by a plan or issuer of a service code to another service code, or the alteration, addition, or removal by a plan or issuer of a modifier, if the changed code or modifier is associated with a lower qualifying payment amount than the service code or modifier billed by the provider, facility, or provider of air ambulance services.

(b) *Methodology for calculation of median contracted rate*—(1) *In general.* The median contracted rate for an item or service is calculated by arranging in order from least to greatest the contracted rates of all group health plans of the plan sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) or all group or individual health insurance coverage offered by the issuer in the same insurance market for the same or similar item or service that is provided by a provider in the same or similar specialty or facility of the same or similar facility type and provided in the geographic region in which the item or service is furnished and selecting the middle number. If there are an even number of contracted rates, the median contracted rate is the average of the middle two contracted rates. In determining the median contracted rate, the amount negotiated under each contract is treated as a separate amount. If a plan or issuer has a contract with a provider group or facility, the rate negotiated with that provider group or facility under the contract is treated as a single contracted rate if the same amount applies with respect to all providers of such provider group or facility under the single contract. However, if a plan or issuer has a contract with multiple providers, with separate negotiated rates with each particular provider,

each unique contracted rate with an individual provider constitutes a single contracted rate. Further, if a plan or issuer has separate contracts with individual providers, the contracted rate under each such contract constitutes a single contracted rate (even if the same amount is paid to multiple providers under separate contracts).

(2) *Calculation rules.* In calculating the median contracted rate, a plan or issuer must:

(i) Calculate the median contracted rate with respect to all plans of such sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) or all coverage offered by such issuer that are offered in the same insurance market;

(ii) Calculate the median contracted rate using the full contracted rate applicable to the service code, except that the plan or issuer must—

(A) Calculate separate median contracted rates for CPT code modifiers ''26'' (professional component) and ''TC'' (technical component);

(B) For anesthesia services, calculate a median contracted rate for the anesthesia conversion factor for each service code;

(C) For air ambulance services, calculate a median contracted rate for the air mileage service codes (A0435 and A0436); and

(D) Where contracted rates otherwise vary based on applying a modifier code, calculate a separate median contracted rate for each such service code-modifier combination;

(iii) In the case of payments made by a plan or issuer that are not on a fee-for-service basis (such as bundled or capitation payments), calculate a median contracted rate for each item or service using the underlying fee schedule rates for the relevant items or services. If the plan or issuer does not have an underlying fee schedule rate for the item or service, it must use the derived amount to calculate the median contracted rate; and

(iv) Exclude risk sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments.

(3) *Provider specialties; facility types.* (i) If a plan or issuer has contracted rates that vary based on provider specialty for a service code, the median contracted rate is calculated separately for each provider specialty, as applicable.

(ii) If a plan or issuer has contracted rates for emergency services that vary based on facility type for a service code, the median contracted rate is calculated separately for each facility of the same or similar facility type.

(c) *Methodology for calculation of the qualifying payment amount*—(1) *In general.* (i) For an item or service (other than items or services described in paragraphs (c)(1)(iii) through (vii) of this section) furnished during 2022, the plan or issuer must calculate the qualifying payment amount by increasing the median contracted rate (as determined in accordance with paragraph (b) of this section) for the same or similar item or service under such plans or coverage, respectively, on January 31, 2019, by the combined percentage increase as published by the Department of the Treasury and the Internal Revenue Service to reflect the percentage increase in the CPI–U over 2019, such percentage increase over 2020, and such percentage increase over 2021.

(A) The combined percentage increase for 2019, 2020, and 2021 will be published in guidance by the Internal Revenue Service. The Department of the Treasury and the Internal Revenue Service will calculate the percentage increase using the CPI–U published by the Bureau of Labor Statistics of the Department of Labor.

(B) For purposes of this paragraph (c)(1)(i), the CPI–U for each calendar year is the average of the CPI–U as of the close of the 12-month period ending on August 31 of the calendar year, rounded to 10 decimal places.

(C) The combined percentage increase for 2019, 2020, and 2021 will be calculated as:

(CPI–U 2019/CPI–U 2018) × (CPI–U 2020/CPI–U 2019) × (CPI–U 2021/CPI–U 2020)

(ii) For an item or service (other than items or services described in paragraphs (c)(1)(iii) through (vii) of this section) furnished during 2023 or a subsequent year, the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under

paragraph (c)(1)(i) of this section, for such an item or service furnished in the immediately preceding year, by the percentage increase as published by the Department of the Treasury and the Internal Revenue Service.

(A) The percentage increase for any year after 2022 will be published in guidance by the Internal Revenue Service. The Department of the Treasury and Internal Revenue Service will calculate the percentage increase using the CPI–U published by the Bureau of Labor Statistics of the Department of Labor.

(B) For purposes of this paragraph (c)(1)(ii), the CPI–U for each calendar year is the average of the CPI–U as of the close of the 12-month period ending on August 31 of the calendar year, rounded to 10 decimal places.

(C) The combined percentage increase for any year will be calculated as CPI–U present year/CPI–U prior year.

(iii) For anesthesia services furnished during 2022, the plan or issuer must calculate the qualifying payment amount by first increasing the median contracted rate for the anesthesia conversion factor (as determined in accordance with paragraph (b) of this section) for the same or similar item or service under such plans or coverage, respectively, on January 31, 2019, in accordance with paragraph (c)(1)(i) of this section (referred to in this section as the indexed median contracted rate for the anesthesia conversion factor). The plan or issuer must then multiply the indexed median contracted rate for the anesthesia conversion factor by the sum of the base unit, time unit, and physical status modifier units of the participant, beneficiary, or enrollee to whom anesthesia services are furnished to determine the qualifying payment amount.

(A) The base units for an anesthesia service code are the base units for that service code specified in the most recent edition (as of the date of service) of the American Society of Anesthesiologists Relative Value Guide.

(B) The time unit is measured in 15-minute increments or a fraction thereof.

(C) The physical status modifier on a claim is a standard modifier describing the physical status of the patient and is used to distinguish between various levels of complexity of the anesthesia services provided, and is expressed as a unit with a value between zero (0) and three (3).

(D) The anesthesia conversion factor is expressed in dollars per unit and is a contracted rate negotiated with the plan or issuer.

(iv) For anesthesia services furnished during 2023 or a subsequent year, the plan or issuer must calculate the qualifying payment amount by first increasing the indexed median contracted rate for the anesthesia conversion factor, determined under paragraph (c)(1)(iii) of this section for such services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii) of this section. The plan or issuer must then multiply that amount by the sum of the base unit, time unit, and physical status modifier units for the participant, beneficiary, or enrollee to whom anesthesia services are furnished to determine the qualifying payment amount.

(v) For air ambulance services billed using the air mileage service codes (A0435 and A0436) that are furnished during 2022, the plan or issuer must calculate the qualifying payment amount for services billed using the air mileage service codes by first increasing the median contracted rate (as determined in accordance with paragraph (b) of this section), in accordance with paragraph (c)(1)(i) of this section (referred to in this section as the indexed median air mileage rate). The plan or issuer must then multiply the indexed median air mileage rate by the number of loaded miles provided to the participant, beneficiary, or enrollee to determine the qualifying payment amount.

(A) The air mileage rate is expressed in dollars per loaded mile flown, is expressed in statute miles (not nautical miles), and is a contracted rate negotiated with the plan or issuer.

(B) The number of loaded miles is the number of miles a patient is transported in the air ambulance vehicle.

(C) The qualifying payment amount for other service codes associated with air ambulance services is calculated in accordance with paragraphs (c)(1)(i) and (ii) of this section.

(vi) For air ambulance services billed using the air mileage service codes (A0435 and A0436) that are furnished during 2023 or a subsequent year, the plan or issuer must calculate the qualifying payment amount by first increasing the indexed median air mileage rate, determined under paragraph (c)(1)(v) of this section for such services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii) of this section. The plan or issuer must then multiply the indexed median air mileage rate by the number of loaded miles provided to the participant, beneficiary, or enrollee to determine the qualifying payment amount.

(vii) For any other items or services for which a plan or issuer generally determines payment for the same or similar items or services by multiplying a contracted rate by another unit value, the plan or issuer must calculate the qualifying payment amount using a methodology that is similar to the methodology required under paragraphs (c)(1)(iii) through (vi) of this section and reasonably reflects the payment methodology for same or similar items or services.

(2) *New plans and coverage.* With respect to a sponsor of a group health plan or health insurance issuer offering group or individual health insurance coverage in a geographic region in which the sponsor or issuer, respectively, did not offer any group health plan or health insurance coverage during 2019—

(i) For the first year in which the group health plan, group health insurance coverage, or individual health insurance coverage, respectively, is offered in such region—

(A) If the plan or issuer has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(1) of this section for items and services that are covered by the plan or coverage and furnished during the first year; and

(B) If the plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region, the plan or issuer must determine the qualifying payment amount for the item or service in accordance with paragraph (c)(3)(i) of this section.

(ii) For each subsequent year the group health plan, group health insurance coverage, or individual health insurance coverage, respectively, is offered in the region, the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under this paragraph (c)(2) for the items and services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii), (iv), or (vi) of this section, as applicable.

(3) *Insufficient information; newly covered items and services.* In the case of a plan or issuer that does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in 2019 (or, in the case of a newly covered item or service, in the first coverage year for such item or service with respect to such plan or coverage if the plan or issuer does not have sufficient information) for an item or service provided in a geographic region—

(i) For an item or service furnished during 2022 (or, in the case of a newly covered item or service, during the first coverage year for the item or service with respect to the plan or coverage), the plan or issuer must calculate the qualifying payment amount by first identifying the rate that is equal to the median of the in-network allowed amounts for the same or similar item or service provided in the geographic region in the year immediately preceding the year in which the item or service is furnished (or, in the case of a newly covered item or service, the year immediately preceding such first coverage year) determined by the plan or issuer, respectively, through use of any eligible database, and then increasing that rate by the percentage increase in the CPI–U over such preceding year. For purposes of this section, in cases in which an eligible database is used to determine the qualifying payment amount with respect to an item or service furnished during a calendar year, the plan or issuer must use the

same database for determining the qualifying payment amount for that item or service furnished through the last day of the calendar year, and if a different database is selected for some items or services, the basis for that selection must be one or more factors not directly related to the rate of those items or services (such as sufficiency of data for those items or services).

(ii) For an item or service furnished in a subsequent year (before the first sufficient information year for such item or service with respect to such plan or coverage), the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(3)(i) of this section or this paragraph (c)(3)(ii), as applicable, for such item or service for the year immediately preceding such subsequent year, by the percentage increase in CPI–U over such preceding year;

(iii) For an item or service furnished in the first sufficient information year for such item or service with respect to such plan or coverage, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(1)(i), (iii), or (v) of this section, as applicable, except that in applying such paragraph to such item or service, the reference to 'furnished during 2022' is treated as a reference to furnished during such first sufficient information year, the reference to 'in 2019' is treated as a reference to such sufficient information year, and the increase described in such paragraph is not applied; and

(iv) For an item or service furnished in any year subsequent to the first sufficient information year for such item or service with respect to such plan or coverage, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(1)(ii), (iv), or (vi) of this section, as applicable, except that in applying such paragraph to such item or service, the reference to 'furnished during 2023 or a subsequent year' is treated as a reference to furnished during the year after such first sufficient information year or a subsequent year.

(4) *New service codes.* In the case of a plan or issuer that does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section and determine the qualifying payment amount under paragraphs (c)(1) through (3) of this section because the item or service furnished is billed under a new service code—

(i) For an item or service furnished during 2022 (or, in the case of a newly covered item or service, during the first coverage year for the item or service with respect to the plan or coverage), the plan or issuer must identify a reasonably related service code that existed in the immediately preceding year and—

(A) If the Centers for Medicare & Medicaid Services has established a Medicare payment rate for the item or service billed under the new service code, the plan or issuer must calculate the qualifying payment amount by first calculating the ratio of the rate that Medicare pays for the item or service billed under the new service code compared to the rate that Medicare pays for the item or service billed under the related service code, and then multiplying the ratio by the qualifying payment amount for an item or service billed under the related service code for the year in which the item or service is furnished.

(B) If the Centers for Medicare & Medicaid Services has not established a Medicare payment rate for the item or service billed under the new service code, the plan or issuer must calculate the qualifying payment amount by first calculating the ratio of the rate that the plan or issuer reimburses for the item or service billed under the new service code compared to the rate that the plan or issuer reimburses for the item or service billed under the related service code, and then multiplying the ratio by the qualifying payment amount for an item or service billed under the related service code.

(ii) For an item or service furnished in a subsequent year (before the first sufficient information year for such item or service with respect to such plan or coverage or before the first year for which an eligible database has sufficient information to a calculate a rate under paragraph (c)(3)(i) of this section in the immediately preceding year), the plan or issuer must calculate

the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(4)(i) of this section or this paragraph (c)(4)(ii), as applicable, for such item or service for the year immediately preceding such subsequent year, by the percentage increase in CPI–U over such preceding year;

(iii) For an item or service furnished in the first sufficient information year for such item or service with respect to such plan or coverage or the first year for which an eligible database has sufficient information to calculate a rate under paragraph (c)(3)(i) of this section in the immediately preceding year, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(3) of this section.

(d) *Information to be shared about qualifying payment amount.* In cases in which the recognized amount with respect to an item or service furnished by a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services is the qualifying payment amount, the plan or issuer must provide in writing, in paper or electronic form, to the provider or facility, as applicable—

(1) With each initial payment or notice of denial of payment under § 149.110, § 149.120, or § 149.130:

(i) The qualifying payment amount for each item or service involved;

(ii) If the qualifying payment amount is based on a downcoded service code or modifier—

(A) A statement that the service code or modifier billed by the provider, facility, or provider of air ambulance services was downcoded;

(B) An explanation of why the claim was downcoded, which must include a description of which service codes were altered, if any, and a description of which modifiers were altered, added, or removed, if any; and

(C) The amount that would have been the qualifying payment amount had the service code or modifier not been downcoded;

(iii) A statement to certify that, based on the determination of the plan or issuer—

(A) The qualifying payment amount applies for purposes of the recognized amount (or, in the case of air ambulance services, for calculating the participant's, beneficiary's, or enrollee's cost sharing); and

(B) Each qualifying payment amount shared with the provider or facility was determined in compliance with this section;

(iv) A statement that if the provider or facility, as applicable, wishes to initiate a 30-day open negotiation period for purposes of determining the amount of total payment, the provider or facility may contact the appropriate person or office to initiate open negotiation, and that if the 30-day negotiation period does not result in a determination, generally, the provider or facility may initiate the independent dispute resolution process within 4 days after the end of the open negotiation period; and

(v) Contact information, including a telephone number and email address, for the appropriate person or office to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service.

(2) In a timely manner upon request of the provider or facility:

(i) Information about whether the qualifying payment amount for items and services involved included contracted rates that were not on a fee-for-service basis for those specific items and services and whether the qualifying payment amount for those items and services was determined using underlying fee schedule rates or a derived amount;

(ii) If a plan or issuer uses an eligible database under paragraph (c)(3) of this section to determine the qualifying payment amount, information to identify which database was used; and

(iii) If a related service code was used to determine the qualifying payment amount for an item or service billed under a new service code under paragraph (c)(4)(i) or (ii) of this section, information to identify the related service code; and

(iv) If applicable, a statement that the plan's or issuer's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments for

the items and services involved (as applicable) that were excluded for purposes of calculating the qualifying payment amount.

(e) *Certain access fees to databases.* In the case of a plan or issuer that, pursuant to this section, uses an eligible database to determine the qualifying payment amount for an item or service, the plan or issuer is responsible for any costs associated with accessing such database.

(f) *Audits.* The procedures described in part 150 of this subchapter apply with respect to ensuring that a plan or coverage is in compliance with the requirement of applying a qualifying payment amount under this subpart and ensuring that such amount so applied satisfies the requirements under this section, as applicable.

(g) *Applicability date.* The provisions of this section are applicable for plan years or in the individual market, policy years beginning on or after January 1, 2022, except that paragraph (a)(18) of this section regarding the definition of the term ''downcode'' and paragraph (d)(1)(ii) of this section regarding additional information that must be provided if the qualifying payment amount is based on a downcoded service code or modifier are applicable with respect to items or services provided or furnished on or after October 25, 2022, for plan years or in the individual market, policy years beginning on or after January 1, 2022.

[86 FR 36970, July 13, 2021, as amended at 87 FR 52652, Aug. 26, 2022]

§ 149.150 Complaints process for surprise medical bills regarding group health plans and group and individual health insurance coverage.

(a) *Scope and definitions*—(1) *Scope.* This section establishes a process to receive and resolve complaints regarding information that a specific group health plan or health insurance issuer offering group or individual health insurance coverage may be failing to meet the requirements under this subpart, which may warrant an investigation.

(2) *Definitions.* In this section—

(i) *Complaint* means a communication, written or oral, that indicates there has been a potential violation of the requirements under subpart B of this part, whether or not a violation actually occurred.

(ii) *Complainant* means any individual, or their authorized representative, who files a complaint as defined in paragraph (a)(2)(i) of this section.

(b) *Complaints process.* (1) HHS will consider the date a complaint is filed to be the date upon which HHS receives an oral or written statement that identifies information about the complaint sufficient to identify the parties involved and the action or inaction complained of.

(2) HHS will notify complainants, by oral or written means, of receipt of the complaint no later than 60 business days after the complaint is received. HHS will include a response acknowledging receipt of the complaint, notifying the complainant of their rights and obligations under the complaints process, and describing the next steps of the complaints resolution process. As part of the response, HHS may request additional information needed to process the complaint. Such additional information may include:

(i) Explanations of benefits;

(ii) Processed claims;

(iii) Information about the health care provider, facility, or provider of air ambulance services involved;

(iv) Information about the group health plan or health insurance issuer covering the individual;

(v) Information to support a determination regarding whether the service was an emergency service or non-emergency service;

(vi) The summary plan description, policy, certificate, contract of insurance, membership booklet, outline of coverage, or other evidence of coverage the plan or issuer provides to participants, beneficiaries, or enrollees;

(vii) Documents regarding the facts in the complaint in the possession of, or otherwise attainable by, the complainant; or

(viii) Any other information HHS may need to make a determination of facts for an investigation.

(3) HHS will make reasonable efforts consistent with agency practices to notify the complainant of the outcome of the complaint after the submission is processed through appropriate methods

as determined by HHS. A complaint is considered processed after HHS has reviewed the complaint and accompanying information and made an outcome determination. Based on the nature of the complaint and the plan or issuer involved, HHS may—

(i) Refer the complainant to another appropriate Federal or State resolution process;

(ii) Notify the complainant and make reasonable efforts to refer the complainant to the appropriate State or Federal regulatory authority if HHS receives a complaint where another entity has enforcement jurisdiction over the plan or issuer;

(iii) Refer the plan or issuer for an investigation for enforcement action under 45 CFR part 150; or

(iv) Provide the complainant with an explanation of the resolution of the complaint and any corrective action taken.

Subpart C [Reserved]

Subpart D—Additional Patient Protections

§ 149.310 Choice of health care professional.

(a) *Choice of health care professional*—(1) *Designation of primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(1)(i) of this section is to be construed to prohibit the application of reasonable and appropriate geographic limitations with respect to the selection of primary care providers, in accordance with the terms of the plan or coverage, the underlying provider contracts, and applicable State law.

(iii) *Example.* The rules of this paragraph (a)(1) are illustrated by the following example:

(A) *Facts.* A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any primary care provider participating in the plan's network who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until the individual has made a designation. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(B) *Conclusion.* In this *Example,* the plan has satisfied the requirements of paragraph (a) of this section.

(2) *Designation of pediatrician as primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the participant, beneficiary, or enrollee to designate a physician (allopathic or osteopathic) who specializes in pediatrics (including pediatric subspecialties, based on the scope of that provider's license under applicable State law) as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance

coverage with respect to coverage of pediatric care.

(iii) *Examples.* The rules of this paragraph (a)(2) are illustrated by the following examples:

(A) *Example 1—(1) Facts.* A group health plan's HMO designates for each participant a physician who specializes in internal medicine to serve as the primary care provider for the participant and any beneficiaries. Participant *A* requests that Pediatrician *B* be designated as the primary care provider for *A*'s child. *B* is a participating provider in the HMO's network and is available to accept the child.

(*2*) *Conclusion.* In this *Example 1,* the HMO must permit *A*'s designation of *B* as the primary care provider for *A*'s child in order to comply with the requirements of this paragraph (a)(2).

(B) *Example 2—(1) Facts.* Same facts as *Example 1* (paragraph (a)(2)(iii)(A) of this section), except that *A* takes *A*'s child to *B* for treatment of the child's severe shellfish allergies. *B* wishes to refer *A*'s child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network, and it therefore refuses to authorize the referral.

(*2*) *Conclusion.* In this *Example 2,* the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of *A*'s coverage.

(3) *Patient access to obstetrical and gynecological care*—(i) *General rights*—(A) *Direct access.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, described in paragraph (a)(3)(ii) of this section, may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual (including a person other than a physician) who is authorized under applicable State law to provide obstetrical or gynecological care.

(B) *Obstetrical and gynecological care.* A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) *Application of paragraph.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, is described in this paragraph (a)(3) if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(iii) *Construction.* Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(iv) *Examples.* The rules of this paragraph (a)(3) are illustrated by the following examples:

(A) *Example 1—(1) Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant *A*, a female, requests a gynecological exam with Physician *B*, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from *A*'s designated primary care provider for the gynecological exam.

(*2*) *Conclusion.* In this *Example 1,* the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from *A*'s primary care provider prior to obtaning gynecological services.

(B) *Example 2—(1) Facts.* Same facts as *Example 1* (paragraph (a)(3)(iv)(A) of this section) except that *A* seeks gynecological services from *C*, an out-of-network provider.

(*2*) *Conclusion.* In this *Example 2,* the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because *C* is not a participating health care provider.

(C) *Example 3—(1) Facts.* Same facts as *Example 1* (paragraph (a)(3)(iv)(A) of this section) except that the group health plan only requires *B* to inform *A*'s designated primary care physician of treatment decisions.

(*2*) *Conclusion.* In this *Example 3,* the group health plan has not violated the requirements of this paragraph (a)(3) because *A* has direct access to *B* without prior authorization. The fact that the group health plan requires the designated primary care physician to be notified of treatment decisions does not violate this paragraph (a)(3).

(D) *Example 4—(1) Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for uterine fibroid embolization.

(*2*) *Conclusion.* In this *Example 4,* the plan requirement for prior authorization before providing benefits for uterine fibroid embolization does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to obstetrical services, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) *Notice of right to designate a primary care provider*—(i) *In general.* If a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights—

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated;

(B) Under paragraph (a)(2)(i) of this section, with respect to a child, that any participating physician who specializes in pediatrics can be designated as the primary care provider; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) *Timing.* In the case of a group health plan or group health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage. In the case of individual health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance.

(iii) *Model language.* The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary

care providers by participants, beneficiaries, or enrollees, insert:

[Name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider. You have the right to designate any primary care provider who participates in our network and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator or issuer] at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, add:

For children, you may designate a pediatrician as the primary care provider.

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant, beneficiary, or enrollee of a primary care provider, add:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the [plan administrator or issuer] at [insert contact information].

(b) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

Subpart E—Health Care Provider, Health Care Facility, and Air Ambulance Service Provider Requirements

§ 149.410 Balance billing in cases of emergency services.

(a) *In general.* In the case of a participant, beneficiary, or enrollee with benefits under a group health plan or group or individual health insurance coverage offered by a health insurance issuer and who is furnished emergency services (for which benefits are provided under the plan or coverage) with respect to an emergency medical condition with respect to a visit at an emergency department of a hospital or an independent freestanding emergency department—

(1) A nonparticipating emergency facility must not bill, and must not hold liable, the participant, beneficiary, or enrollee for a payment amount for such emergency services (as defined in 26 CFR 54.9816–4T(c)(2), 29 CFR 2590.716–4(c)(2), and §149.110(c)(2), as applicable) that exceeds the cost-sharing requirement for such services (as determined in accordance with 26 CFR 54.9816–4T(b)(3)(ii) and (iii), 29 CFR 2590.716–4(b)(3)(ii) and (iii), and §149.110(b)(3)(ii) and (iii), as applicable).

(2) A nonparticipating provider must not bill, and must not hold liable, the participant, beneficiary, or enrollee for a payment amount for an emergency service (as defined in 26 CFR 54.9816–4T(c)(2), 29 CFR 2590.716–4(c)(2), and §149.110(c)(2), as applicable) furnished to such individual by such provider with respect to such emergency medical condition and visit for which the individual receives emergency services at the hospital or independent freestanding emergency department that exceeds the cost-sharing requirement for such service (as determined in accordance with 26 CFR 54.9816–4T(b)(3)(ii) and (iii), 29 CFR 2590.716–4(b)(3)(ii) and (iii), and §149.110(b)(3)(ii) and (iii), as applicable).

(b) *Notice and consent to be treated by a nonparticipating provider or nonparticipating emergency facility.* The requirements in paragraph (a) of this section do not apply with respect to items and services described in 26 CFR, 54.9816–4T(c)(2)(ii)(A), 29 CFR 2590.716–4(c)(2)(ii)(A), §149.110(c)(2)(ii)(A), as applicable, and are not included as emergency services if all of the following conditions are met:

(1) The attending emergency physician or treating provider determines that the participant, beneficiary, or enrollee is able to travel using nonmedical transportation or nonemergency medical transportation to an available

participating provider or facility located within a reasonable travel distance, taking into account the individual's medical condition. The attending emergency physician's or treating provider's determination is binding on the facility for purposes of this requirement.

(2) The provider or facility furnishing such additional items and services satisfies the notice and consent criteria of §149.420(c) through (g) with respect to such items and services, provided that the written notice additionally satisfies paragraphs (b)(2)(i) and (ii) of this section, as applicable. In applying this paragraph (b)(2), a reference in §149.420 to a nonparticipating provider is deemed to include a nonparticipating emergency facility.

(i) In the case of a participating emergency facility and a nonparticipating provider, the written notice must also include a list of any participating providers at the facility who are able to furnish such items and services involved and notification that the participant, beneficiary, or enrollee may be referred, at their option, to such a participating provider.

(ii) In the case of a nonparticipating emergency facility, the written notice must include the good faith estimated amount that the participant, beneficiary, or enrollee may be charged for items or services furnished by the nonparticipating emergency facility or by nonparticipating providers with respect to the visit at such facility (including any item or service that is reasonably expected to be furnished by the nonparticipating emergency facility or nonparticipating providers in conjunction with such items or services).

(3) The participant, beneficiary, or enrollee (or an authorized representative of such individual) is in a condition to receive the information described in §149.420, as determined by the attending emergency physician or treating provider using appropriate medical judgment, and to provide informed consent under such section, in accordance with applicable State law. For purposes of this section and §149.420, an authorized representative is an individual authorized under State law to provide consent on behalf of the participant, beneficiary, or enrollee, provided that the individual is not a provider affiliated with the facility or an employee of the facility, unless such provider or employee is a family member of the participant, beneficiary, or enrollee.

(4) The provider or facility satisfies any additional requirements or prohibitions as may be imposed under State law.

(c) *Inapplicability of notice and consent exception to certain items and services.* A nonparticipating provider or nonparticipating facility specified in paragraph (a) of this section will always be subject to the prohibitions in paragraph (a) of this section, with respect to items or services furnished as a result of unforeseen, urgent medical needs that arise at the time an item or service is furnished, regardless of whether the nonparticipating provider or nonparticipating emergency facility satisfied the notice and consent criteria in §149.420(c) through (g).

(d) *Retention of certain documents.* A nonparticipating emergency facility (with respect to such facility or any nonparticipating provider at such facility) that obtains from a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage (or an authorized representative of such an individual) a written consent in accordance with §149.420(e), with respect to furnishing an item or service to such an individual, must retain the written notice and consent for at least a 7-year period after the date on which the item or service is so furnished. If a nonparticipating provider obtains a signed consent from a participant, beneficiary, or enrollee, or such individual's authorized representative, the provider may either coordinate with the facility to retain the written notice and consent for a 7-year period, or the provider must retain the written notice and consent for a 7-year period.

(e) *Notification to plan or issuer.* In the case of a participant, beneficiary, or enrollee who is stabilized and furnished additional items and services described in §149.110(c)(2)(ii), a nonparticipating provider or nonparticipating emergency facility must notify the plan or issuer, respectively, when transmitting

the bill for such items and services, either on the bill or in a separate document, as to whether all of the conditions described in paragraph (b) of this section are met with respect to each of the items and services for which the bill is submitted, and if applicable, provide to the plan or issuer a copy of the signed written notice and consent document described in paragraph (b)(2) of this section.

(f) *Applicability date.* The provisions of this section are applicable with respect to emergency services furnished during a plan year (in the individual market, policy year) beginning on or after January 1, 2022.

§ 149.420 Balance billing in cases of non-emergency services performed by nonparticipating providers at certain participating health care facilities.

(a) *In general.* A nonparticipating provider of a group health plan or group or individual health insurance coverage who provides items or services (other than emergency services) for which benefits are provided under the plan or coverage at a participating health care facility must not bill, and must not hold liable, a participant, beneficiary, or enrollee of such plan or coverage for a payment amount for such an item or service furnished by such provider with respect to a visit at the facility that exceeds the cost-sharing requirement for such item or service (as determined in accordance with 26 CFR 54.9816–5T(c)(1) and (2), 29 CFR 2590.717–1(c)(1) and (2), and § 149.120(c)(1) and (2), as applicable), unless the provider (or the participating health care facility on behalf of the provider) satisfies the notice and consent criteria of paragraph (c) of this section.

(b) *Inapplicability of notice and consent exception to certain items and services.* The notice and consent criteria in paragraphs (c) through (i) of this section do not apply, and a nonparticipating provider specified in paragraph (a) of this section will always be subject to the prohibitions in paragraph (a) of this section, with respect to the following services:

(1) Ancillary services, meaning—

(i) Items and services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology, whether provided by a physician or non-physician practitioner;

(ii) Items and services provided by assistant surgeons, hospitalists, and intensivists;

(iii) Diagnostic services, including radiology and laboratory services; and

(iv) Items and services provided by a nonparticipating provider if there is no participating provider who can furnish such item or service at such facility.

(2) Items or services furnished as a result of unforeseen, urgent medical needs that arise at the time an item or service is furnished, regardless of whether the nonparticipating provider satisfied the notice and consent criteria in paragraph (c) of this section.

(c) *Notice and consent to be treated by a nonparticipating provider.* Subject to paragraph (f) of this section, and unless prohibited by State law, a nonparticipating provider satisfies the notice and consent criteria of this paragraph (c) with respect to items or services furnished by the provider to a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage, if the provider (or a participating health care facility on behalf on a nonparticipating provider)—

(1) Provides to the participant, beneficiary, or enrollee a written notice in paper or, as practicable, electronic form, as selected by the individual, that contains the information required under paragraph (d) of this section, provided such written notice is provided:

(i) In accordance with guidance issued by HHS, and in the form and manner specified in such guidance;

(ii) With the consent document, and is provided physically separate from other documents and not attached to or incorporated into any other document; and

(iii) To such participant, beneficiary, or enrollee—

(A) Not later than 72 hours prior to the date on which the individual is furnished such items or services, in the case where the appointment to be furnished such items or services is scheduled at least 72 hours prior to the date on which the individual is to be furnished such items and services; or

(B) On the date the appointment to be furnished such items or services is scheduled, in the case where the appointment is scheduled within 72 hours prior to the date on which such items or services are to be furnished. Where an individual is provided the notice on the same date that the items or services are to be furnished, providers and facilities are required to provide the notice no later than 3 hours prior to furnishing items or services to which the notice and consent requirements apply.

(2) Obtains from the participant, beneficiary, or enrollee the consent described in paragraph (e) of this section to be treated by the nonparticipating provider. An authorized representative may receive the notice on behalf of a participant, beneficiary, or enrollee, and may provide consent on behalf of the participant, beneficiary, or enrollee. For purposes of this section and §149.410, an authorized representative is an individual authorized under State law to provide consent on behalf of the participant, beneficiary, or enrollee, provided that the individual is not a provider affiliated with the facility or an employee of the facility, unless such provider or employee is a family member of the participant, beneficiary, or enrollee. The consent must—

(i) Be provided voluntarily, meaning the individual is able to consent freely, without undue influence, fraud, or duress;

(ii) Be obtained in accordance with, and in the form and manner specified in, guidance issued by HHS; and

(iii) Not be revoked, in writing, by the participant, beneficiary, or enrollee prior to the receipt of items and services to which the consent applies.

(3) Provides a copy of the signed written notice and consent to the participant, beneficiary, or enrollee in-person or through mail or email, as selected by the participant, beneficiary, or enrollee.

(d) *Information required under written notice.* The written notice described in paragraph (c)(1) of this section must be provided in the form and manner specified by HHS in guidance, and must—

(1) State that the health care provider is a nonparticipating provider, with respect to the health plan or coverage.

(2) Include the good faith estimated amount that such nonparticipating provider may charge the participant, beneficiary, or enrollee for the items and services involved (including any item or service that is reasonably expected to be furnished by the nonparticipating provider in conjunction with such items or services), including notification that the provision of the estimate or consent to be treated under paragraph (e) of this section does not constitute a contract with respect to the charges estimated for such items and services or a contract that binds the participant, beneficiary, or enrollee to be treated by that provider or facility.

(3) Provide a statement that prior authorization or other care management limitations may be required in advance of receiving such items or services at the facility.

(4) Clearly state that consent to receive such items and services from such nonparticipating provider is optional and that the participant, beneficiary, or enrollee may instead seek care from an available participating provider, with respect to the plan or coverage, as applicable, and that in such cases the cost-sharing responsibility of the participant, beneficiary, or enrollee would not exceed the responsibility that would apply with respect to such an item or service that is furnished by a participating provider, as applicable, with respect to such plan.

(e) *Consent described to be treated by a nonparticipating provider.* The consent described in this paragraph (e), with respect to a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage who is to be furnished items or services by a nonparticipating provider, must be documented on a form specified by the Secretary, in consultation with the Secretary of Labor, through guidance and provided in accordance with such guidance, that must be signed by the participant, beneficiary, or enrollee before such items and services are furnished and that—

(1) Acknowledges in clear and understandable language that the participant, beneficiary, or enrollee has been—

(i) Provided with the written notice under paragraph (c) of this section, in the form selected by the participant, beneficiary, or enrollee.

(ii) Informed that the payment of such charge by the participant, beneficiary, or enrollee might not accrue toward meeting any limitation that the plan or coverage places on cost sharing, including an explanation that such payment might not apply to an in-network deductible or out-of-pocket maximum applied under the plan or coverage.

(2) States that by signing the consent, the individual agrees to be treated by the nonparticipating provider and understands the individual may be balance billed and subject to cost-sharing requirements that apply to services furnished by the nonparticipating provider.

(3) Documents the time and date on which the participant, beneficiary, or enrollee received the written notice described in paragraph (c) of this section and the time and date on which the individual signed the consent to be furnished such items or services by such nonparticipating provider.

(f) *Language access.* (1) A nonparticipating provider (or the participating health care facility on behalf of the nonparticipating provider) must provide the individual with the choice to receive the written notice and consent document in any of the 15 most common languages in the State in which the applicable facility is located, except that the notice and consent document may instead be available in any of the 15 most common languages in a geographic region that reasonably reflects the geographic region served by the applicable facility; and

(2) If the individual's preferred language is not among the 15 most common languages in which the nonparticipating provider (or the participating health care facility on behalf of the nonparticipating provider) makes the notice and consent document available and the individual cannot understand the language in which the notice and consent document are provided, the notice and consent criteria in paragraph (c) of this section are not met unless the nonparticipating provider (or the participating health care facility on behalf of the nonparticipating provider) has obtained the services of a qualified interpreter to assist the individual with understanding the information contained in the notice and consent document.

(g) *Scope of consent.* The consent described in paragraph (e) of this section will constitute consent only to the receipt of the information provided pursuant to this section and will not constitute a contractual agreement of the participant, beneficiary, or enrollee to any estimated charge or amount included in such information, or to be treated by that provider or facility.

(h) *Retention of certain documents.* A participating health care facility (with respect to nonparticipating providers at such facility) that obtains from a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage a written consent in accordance with paragraph (e) of this section, with respect to furnishing an item or service to such an individual, must retain the written notice and consent for at least a 7-year period after the date on which the item or service is so furnished. If a nonparticipating provider obtains a signed consent from a participant, beneficiary, or enrollee, where the facility does not otherwise obtain the consent on behalf of the provider, the provider may either coordinate with the facility to retain the written notice and consent for a 7-year period, or the provider must retain the written notice and consent for a 7-year period.

(i) *Notification to plan or issuer.* For each item or service furnished by a nonparticipating provider described in paragraph (a) of this section, the provider (or the participating facility on behalf of the nonparticipating provider) must timely notify the plan or issuer that the item or service was furnished during a visit at a participating health care facility, and, if applicable, provide to the plan or issuer a copy of the signed written notice and consent document described in paragraphs (c) and (e) of this section. In instances where, to the extent permitted by this

section, the nonparticipating provider bills the participant, beneficiary, or enrollee directly, the provider may satisfy the requirement to notify the plan or issuer by including the notice with the bill to the participant, beneficiary, or enrollee.

(j) *Applicability date.* The provisions of this section are applicable with respect to items and services furnished during a plan year (in the individual market, policy year) beginning on or after January 1, 2022.

§ 149.430 Provider and facility disclosure requirements regarding patient protections against balance billing.

(a) *In general.* Each health care provider and health care facility (including an emergency department of a hospital and an independent freestanding emergency department) must make publicly available, post on a public website of such provider or facility (if applicable), and provide to any individual who is a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage offered by a health insurance issuer and to whom the provider or facility furnishes items or services, the information described in paragraph (b) of this section regarding patient protections against balance billing, except as provided in paragraphs (e) and (f) of this section. A provider or facility must make the disclosures in accordance with the method and timing requirements set forth in paragraphs (c) and (d) of this section.

(b) *Content.* The disclosures required under this section must include, in clear and understandable language, all the information described in this paragraph (b) (and may include any additional information that does not conflict with that information).

(1) A statement that explains the requirements of and prohibitions applicable to the health care provider or health care facility under sections 2799B–1 and 2799B–2 of the PHS Act and their implementing regulations in §§ 149.410 and 149.420;

(2) If applicable, a statement that explains any State law requirements regarding the amounts such provider or facility may, with respect to an item or service, charge a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage offered by a health insurance issuer with respect to which such provider or facility does not have a contractual relationship, after receiving payment, if any, from the plan or coverage, respectively, for such item or service and any applicable cost-sharing payment from such participant, beneficiary, or enrollee; and

(3) A statement providing contact information for the appropriate State and Federal agencies that an individual may contact if the individual believes the provider or facility has violated a requirement described in the notice.

(c) *Required methods for disclosing information.* Health care providers and health care facilities must provide the disclosure required under this section as follows:

(1) With respect to the required disclosure to be posted on a public website, the information described in paragraph (b) of this section, or a link to such information, must appear on a searchable homepage of the provider's or facility's website. A provider or facility that does not have its own website is not required to make a disclosure under this paragraph (c)(1).

(2) With respect to the required disclosure to the public, a provider or facility must make public the information described in paragraph (b) of this section on a sign posted prominently at the location of the provider or facility. A provider that does not have a publicly accessible location is not required to make a disclosure under this paragraph (c)(2).

(3) With respect to the required disclosure to individuals who are participants, beneficiaries, or enrollees of a group health plan or group or individual health insurance coverage offered by a health insurance issuer, a provider or facility must provide the information described in paragraph (b) of this section in a one-page (double-sided) notice, using print no smaller than 12-point font. The notice must be provided in-person or through mail or email, as selected by the participant, beneficiary, or enrollee.

(d) *Timing of disclosure to individuals.* A health care provider or health care

facility is required to provide the notice to individuals who are participants, beneficiaries, or enrollees of a group health plan or group or individual health insurance coverage offered by a health insurance issuer no later than the date and time on which the provider or facility requests payment from the individual, or with respect to an individual from whom the provider or facility does not request payment, no later than the date on which the provider or facility submits a claim to the group health plan or health insurance issuer.

(e) *Exceptions.* A health care provider is not required to make the disclosures required under this section—

(1) If the provider does not furnish items or services at a health care facility, or in connection with visits at health care facilities; or

(2) To individuals to whom the provider furnishes items or services, if such items or services are not furnished at a health care facility, or in connection with a visit at a health care facility.

(f) *Special rule to prevent unnecessary duplication with respect to health care providers.* To the extent a provider furnishes an item or service covered under the plan or coverage at a health care facility (including an emergency department of a hospital or independent freestanding emergency department), the provider satisfies the requirements of paragraphs (c)(2) and (3) of this section if the facility makes the information available, in the required form and manner, pursuant to a written agreement. Accordingly, if a provider and facility enter into a written agreement under which the facility agrees to make the information required under this section available on a sign posted prominently at the facility and to provide the one-page notice to individuals in compliance with this section, and the facility fails to do so, then the facility, but not the provider, violates the disclosure requirements of this section.

(g) *Applicability date.* The provisions of this section are applicable beginning on January 1, 2022.

§ 149.440 Balance billing in cases of air ambulance services.

(a) *In general.* In the case of a participant, beneficiary, or enrollee with benefits under a group health plan or group or individual health insurance coverage offered by a health insurance issuer who is furnished air ambulance services (for which benefits are available under such plan or coverage) from a nonparticipating provider of air ambulance services, with respect to such plan or coverage, the provider must not bill, and must not hold liable, the participant, beneficiary, or enrollee for a payment amount for the air ambulance services furnished by the provider that is more than the cost-sharing amount for such service (as determined in accordance with 26 CFR 54.9817–1T(b)(1) and (2), 29 CFR 2590.717–1(b)(1) and (2), and § 149.130(b)(1) and (2), as applicable).

(b) *Applicability date.* The provisions of this section are applicable with respect to air ambulance services furnished during a plan year (in the individual market, policy year) beginning on or after January 1, 2022.

§ 149.450 Complaint process for balance billing regarding providers and facilities.

(a) *Scope and definitions*—(1) *Scope.* This section establishes a process for HHS to receive and resolve complaints regarding information that a health care provider, provider of air ambulance services, or health care facility may be failing to meet the requirements under subpart E or subpart G of this part, which may warrant an investigation.

(2) *Definitions.* In this section—

(i) Complaint means a communication, written, or oral, that indicates there has been a potential violation of the requirements under this subpart or subpart G of this part, whether or not a violation actually occurred.

(ii) *Complainant* means any individual, or their authorized representative, who files a complaint as defined in paragraph (a)(2)(i) of this section.

(b) *Complaints process.* (1) HHS will consider the date a complaint is filed to be the date upon which HHS receives an oral, written, or electronic statement that identifies information about the complaint sufficient to identify the

parties involved and the action or inaction complained of.

(2) HHS will notify complainants, by oral or written means, of receipt of the complaint no later than 60 business days after the complaint is received. HHS will include a response acknowledging receipt of the complaint, notifying the complainant of their rights and obligations under the complaints process, and describing the next steps of the complaints resolution process. HHS may request additional information that may be needed to process the complaint as part of the response. Such additional information may include:

(i) Health care provider, air ambulance provider, or health care facility bills;

(ii) Health care provider, air ambulance provider, or health care facility network status;

(iii) Information regarding the participant's, beneficiary's, or enrollee's health care plan or health insurance coverage;

(iv) Information to support a determination regarding whether the service was an emergency service or non-emergency service;

(v) Documents regarding the facts in the complaint in the possession of, or otherwise attainable by, the complainant; or

(vi) Any other information HHS needs to make a determination of facts for an investigation.

(3) HHS will make reasonable efforts consistent with agency practices to notify the complainant of the outcome of the complaint after the submission is processed through appropriate methods as determined by HHS. A complaint is considered processed after HHS has reviewed the complaint and accompanying information and made an outcome determination. Based on the nature of the complaint, HHS may—

(i) Refer the complainant to another appropriate Federal or State resolution process;

(ii) Notify the complainant and make reasonable efforts to refer the complainant to the appropriate State or Federal regulatory authority if HHS receives a complaint where another entity has enforcement jurisdiction over the health care provider, air ambulance provider or health care facility;

(iii) Refer the health care provider, air ambulance provider or health care facility for an investigation for enforcement action under 45 CFR part 150; or

(iv) Provide the complainant with an explanation of resolution and any corrective action taken.

[86 FR 36970, July 13, 2021, as amended at 86 FR 56124, Oct. 7, 2021]

Subpart F—Independent Dispute Resolution Process

SOURCE: 86 FR 56124, Oct. 7, 2021, unless otherwise noted.

§ 149.510 Independent dispute resolution process.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements with respect to the independent dispute resolution (IDR) process (referred to in this section as the Federal IDR process) under which a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services (as applicable), and a group health plan or health insurance issuer offering group or individual health insurance coverage completes a requisite open negotiation period and at least one party submits a notification under paragraph (b) of this section to initiate the Federal IDR process under paragraph (c) of this section, and under which an IDR entity (as certified under paragraph (e) of this section) determines the amount of payment under the plan or coverage for an item or service furnished by the provider or facility.

(2) *Definitions.* Unless otherwise stated, the definitions in §149.30 of this part apply to this section. Additionally, for purposes of this section, the following definitions apply:

(i) *Batched items and services* means multiple qualified IDR items or services that are considered jointly as part of one payment determination by a certified IDR entity for purposes of the Federal IDR process. In order for a qualified IDR item or service to be included in a batched item or service, the qualified IDR item or service must meet the criteria set forth in paragraph (c)(3) of this section.

(ii) *Breach* means the acquisition, access, use, or disclosure of individually identifiable health information (IIHI) in a manner not permitted under paragraph (e)(2)(v) of this section that compromises the security or privacy of the IIHI.

(A) Breach excludes:

(*1*) Any unintentional acquisition, access, or use of IIHI by personnel, a contractor, or a subcontractor of a certified IDR entity that is acting under the authority of that certified IDR entity, if the acquisition, access, or use was made in good faith and within the scope of that authority and that does not result in further use or disclosure in a manner not permitted under paragraph (e)(2)(v) of this section.

(*2*) Any inadvertent disclosure by a person who is authorized to access IIHI at a certified IDR entity to another person authorized to access IIHI at the same certified IDR entity, and the information received as a result of the disclosure is not further used or disclosed in a manner not permitted under paragraph (e)(2)(v) of this section.

(*3*) A disclosure of IIHI in which a certified IDR entity has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

(B) Except as provided in paragraph (a)(2)(ii)(A) of this definition, access, use, or disclosure of IIHI in a manner not permitted under paragraph (e)(2)(v) of this section is presumed to be a breach unless the certified IDR entity demonstrates that there is a low probability that the security or privacy of the IIHI has been compromised based on a risk assessment encompassing at least the following factors:

(*1*) The nature and extent of the IIHI involved, including the types of identifiers and the likelihood of re-identification;

(*2*) The unauthorized person who used the IIHI or to whom the disclosure was made;

(*3*) Whether the IIHI was actually acquired or viewed; and

(*4*) The extent to which the risk to the IIHI has been mitigated.

(iii) *Certified IDR entity* means an entity responsible for conducting determinations under paragraph (c) of this section that meets the certification criteria specified in paragraph (e) of this section and that has been certified by the Secretary, jointly with the Secretaries of Labor and the Treasury.

(iv) *Conflict of interest* means, with respect to a party to a payment determination, or certified IDR entity, a material relationship, status, or condition of the party, or certified IDR entity that impacts the ability of the certified IDR entity to make an unbiased and impartial payment determination. For purposes of this section, a conflict of interest exists when a certified IDR entity is:

(A) A group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term, limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(B) An affiliate or a subsidiary of a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(C) An affiliate or subsidiary of a professional or trade association representing group health plans; health insurance issuers offering group health insurance coverage, individual health insurance coverage, or short-term limited duration insurance; carriers offering a health benefits plan under 5 U.S.C. 8902; or providers, facilities, or providers of air ambulance services.

(D) A certified IDR entity, that has, or that has any personnel, contractors, or subcontractors assigned to a determination who have, a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the plan, issuer, or carrier offering a health benefits plan under 5 U.S.C. 8902; the plan or coverage administrator, plan or coverage fiduciaries, or plan, issuer or carrier employees; the health care provider, the health care provider's group or practice

association; the provider of air ambulance services, the provider of air ambulance services' group or practice association, or the facility that is a party to the dispute.

(v) *Credible information* means information that upon critical analysis is worthy of belief and is trustworthy.

(vi) *IDR entity* means an entity that may apply or has applied for certification to conduct determinations under paragraph (c) of this section, and that currently is not certified by the Secretary, jointly with the Secretaries of Labor and the Treasury, pursuant to paragraph (e) of this section.

(vii) *Individually identifiable health information (IIHI)* means any information, including demographic data, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(A) That identifies the individual; or

(B) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(viii) *Material familial relationship* means any relationship as a spouse, domestic partner, child, parent, sibling, spouse's or domestic partner's parent, spouse's or domestic partner's sibling, spouse's or domestic partner's child, child's parent, child's spouse or domestic partner, or sibling's spouse or domestic partner.

(ix) *Material financial relationship* means any financial interest of more than five percent of total annual revenue or total annual income of a certified IDR entity or an officer, director, or manager thereof, or of a reviewer or reviewing physician employed or engaged by a certified IDR entity to conduct or participate in any review in the Federal IDR process. The terms annual revenue and annual income do not include mediation fees received by mediators who are also arbitrators, provided that the mediator acts in the capacity of a mediator and does not represent a party in the mediation.

(x) *Material professional relationship* means any physician-patient relationship, any partnership or employment relationship, any shareholder or similar ownership interest in a professional corporation, partnership, or other similar entity; or any independent contractor arrangement that constitutes a material financial relationship with any expert used by the certified IDR entity or any officer or director of the certified IDR entity.

(xi) *Qualified IDR item or service* means an item or service:

(A) That is an emergency service furnished by a nonparticipating provider or nonparticipating facility subject to the protections of 26 CFR 54.9816–4T, 29 CFR 2590.716–4, or §149.110, as applicable, for which the conditions of §149.410(b) are not met, or an item or service furnished by a nonparticipating provider at a participating health care facility, subject to the requirements of 26 CFR 54.9816–5T, 29 CFR 2590.717–5, or §149.120, as applicable, for which the conditions of §149.420(c)–(i) are not met, or air ambulance services furnished by a nonparticipating provider of air ambulance services subject to the protections of 26 CFR 54.9817–1T, 29 CFR 2590.717–1, or §149.130, as applicable, and for which the out-of-network rate is not determined by reference to an All-Payer Model Agreement under section 1115A of the Social Security Act or a specified State law as defined in §149.30;

(B) With respect to which a provider or facility (as applicable) or group health plan or health insurance issuer offering group or individual health insurance coverage submits a notification under paragraph (b)(2) of this section;

(C) That is not an item or service that is the subject of an open negotiation under paragraph (b)(1) of this section; and

(D) That is not an item or service for which a notification under paragraph (b)(2) of this section is submitted during the 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, but that may include such an item or service if the notification is submitted during the subsequent 30-business-day period under paragraph (c)(4)(vi)(C) of this section.

(xii) *Unsecured IIHI* means IIHI that is not rendered unusable, unreadable,

or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor.

(b) *Determination of payment amount through open negotiation and initiation of the Federal IDR process*—(1) *Determination of payment amount through open negotiation*—(i) *In general.* With respect to an item or service that meets the requirements of paragraph (a)(2)(xii)(A) of this section, the provider, facility, or provider of air ambulance services or the group health plan or health insurance issuer offering group or individual health insurance coverage may, during the 30-business-day period beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or notice of denial of payment regarding the item or service, initiate an open negotiation period for purposes of determining the out-of-network rate for such item or service. To initiate the open negotiation period, a party must send a notice to the other party (open negotiation notice) in accordance with paragraph (b)(1)(ii) of this section.

(ii) *Open negotiation notice*—(A) *Content.* The open negotiation notice must include information sufficient to identify the item(s) and service(s) (including the date(s) the item(s) or service(s) were furnished, the service code, and initial payment amount, if applicable), an offer of an out-of-network rate, and contact information for the party sending the open negotiation notice.

(B) *Manner.* The open negotiation notice must be provided, using the standard form developed by the Secretary, in writing within 30 business days beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or a notice of denial of payment from the plan or issuer regarding the item or service. The day on which the open negotiation notice is first sent by a party is the date the 30-business-day open negotiation period begins. This notice may be provided to the other party electronically (such as by email) if the following two conditions are satisfied—

(*1*) The party sending the open negotiation notice has a good faith belief that the electronic method is readily accessible by the other party; and

(*2*) The notice is provided in paper form free of charge upon request.

(2) *Initiating the Federal IDR process*—(i) *In general.* With respect to an item or service for which the parties do not agree upon an out-of-network rate by the last day of the open negotiation period under paragraph (b)(1) of this section, either party may initiate the Federal IDR process. To initiate the Federal IDR process, a party must submit a written notice of IDR initiation to the other party and to the Secretary, using the standard form developed by the Secretary, during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period.

(ii) *Exception for items and services provided by certain nonparticipating providers and facilities.* A party may not initiate the Federal IDR process with respect to an item or service if, with respect to that item or service, the party knows (or reasonably should have known) that the provider or facility provided notice and received consent under 45 CFR 149.410(b) or 149.420(c) through (i).

(iii) *Notice of IDR initiation*—(A) *Content.* The notice of IDR initiation must include:

(*1*) Information sufficient to identify the qualified IDR items or services under dispute (and whether the qualified IDR items or services are designated as batched items and services as described in paragraph (c)(3) of this section), including the date(s) and location the item or service was furnished, the type of item or service (such as whether the qualified IDR item or service is an emergency service as defined in 26 CFR 54.9816–4T(c)(2)(i), 29 CFR 2590.716–4(c)(2)(i), or §149.110(c)(2)(i), as applicable, an emergency service as defined in 26 CFR 54.9816–4T(c)(2)(ii), 29 CFR 2590.716–4(c)(2)(ii), or §149.110(c)(2)(ii), as applicable, or a nonemergency service; and whether any service is a professional service or facility-based service), corresponding service codes, place of service code, the amount of cost sharing allowed, and the amount of the initial payment made for the qualified IDR item or service, if applicable;

(*2*) Names of the parties involved and contact information, including name, email address, phone number, and mailing address;

(*3*) State where the qualified IDR item or service was furnished;

(*4*) Commencement date of the open negotiation period under paragraph (b)(1) of this section;

(*5*) Preferred certified IDR entity;

(*6*) An attestation that the items and services under dispute are qualified IDR items or services;

(*7*) Qualifying payment amount;

(*8*) Information about the qualifying payment amount as described in §149.140(d); and

(*9*) General information describing the Federal IDR process as specified by the Secretary.

(B) *Manner*. The initiating party must provide written notice of IDR initiation to the other party. The initiating party may satisfy this requirement by furnishing the notice of IDR initiation to the other party electronically (such as by email) if the following two conditions are satisfied—

(*1*) The initiating party has a good faith belief that the electronic method is readily accessible by the other party; and

(*2*) The notice is provided in paper form free of charge upon request.

(C) *Notice to the Secretary*. The initiating party must also furnish the notice of IDR initiation to the Secretary by submitting the notice through the Federal IDR portal. The initiation date of the Federal IDR process will be the date of receipt by the Secretary.

(c) *Federal IDR process following initiation*—(1) *Selection of certified IDR entity*—(i) *In general*. The plan or issuer or the provider, facility, or provider of air ambulance services receiving the notice of IDR initiation under paragraph (b)(2) of this section may agree or object to the preferred certified IDR entity identified in the notice of IDR initiation. If the party in receipt of the notice of IDR initiation fails to object within 3 business days, the preferred certified IDR entity identified in the notice of IDR initiation will be selected and will be treated as jointly agreed to by the parties, provided that the certified IDR entity does not have a conflict of interest. If the party in receipt of the notice of IDR initiation objects, that party must notify the initiating party of the objection and propose an alternative certified IDR entity. The initiating party must then agree or object to the alternative certified IDR entity; if the initiating party fails to agree or object to the alternative certified IDR entity, the alternative certified IDR entity will be selected and will be treated as jointly agreed to by the parties. In order to select a preferred certified IDR entity, the plan or issuer and the provider, facility, or provider of air ambulance services must jointly agree on a certified IDR entity not later than 3 business days after the initiation date of the Federal IDR process. If the plan or issuer and the provider, facility, or provider of air ambulance services fail to agree upon a certified IDR entity within that time, the Secretary shall select a certified IDR entity in accordance with paragraph (c)(1)(iv) of this section.

(ii) *Requirements for selected certified IDR entity*. The certified IDR entity selected must be an IDR entity certified under paragraph (e) of this section, that:

(A) Does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(B) Ensures that assignment of personnel to a payment determination and decisions regarding hiring, compensation, termination, promotion, or other similar matters related to personnel assigned to the dispute are not made based upon the likelihood that the assigned personnel will support a particular party to the determination being disputed other than as outlined under paragraph (c)(4)(iii) of this section; and

(C) Ensures that any personnel assigned to a payment determination do not have any conflicts of interests as defined in paragraph (a)(2) of this section regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b).

(iii) *Notice of certified IDR entity selection*. Upon the selection of a certified IDR entity, in accordance with paragraph (c)(1)(i) of this section, the plan

or issuer or the provider or emergency facility that submitted the notice of IDR initiation under paragraph (b)(2) of this section must notify the Secretary of the selection as soon as reasonably practicable, but no later than 1 business day after such selection, through the Federal IDR portal. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also provide information regarding the Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of certified IDR entity selection must be submitted.

(A) *Content.* If the parties have agreed on the selection of a certified IDR entity or the party in receipt of the notice of IDR initiation has not objected to the other party's selection, the notice of the certified IDR entity selection must include the following information:

(*1*) Name of the certified IDR entity;

(*2*) The certified IDR entity number; and

(*3*) Attestation by both parties, or by the initiating party if the non-initiating party fails to object to the selection of the certified IDR entity, that the selected certified IDR entity meets the requirements of paragraph (c)(1)(ii) of this section.

(B) [Reserved]

(iv) *Failure to select a certified IDR entity.* If the plan or issuer and the provider, facility, or provider of air ambulance services fail to select a certified IDR entity in accordance with paragraph (c)(1)(i) of this section, the initiating party must notify the Secretary of the failure no later than 1 business day after the date of such failure (or in other words, 4 business days after initiation of the Federal IDR process) by electronically submitting the notice as described in paragraph (c)(1)(iii) of this section but indicating that the parties have failed to select a certified IDR entity. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also provide information regarding Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of failure to select must be submitted. Upon notification of the failure of the parties to select a certified IDR entity, the Secretary will select a certified IDR entity that charges a fee within the allowed range of certified IDR entity fees through a random selection method not later than 6 business days after the date of initiation of the Federal IDR process and will notify the plan or issuer and the provider or facility of the selection. If there are insufficient certified IDR entities that charge a fee within the allowed range of certified IDR entity fees available to arbitrate the dispute, the Secretary, jointly with the Secretary of the Treasury and Secretary of Labor, will select a certified IDR entity that has received approval, as described in paragraph (e)(2)(vi)(B) of this section, to charge a fee outside of the allowed range of certified IDR entity fees.

(v) *Review by certified IDR entity.* After selection by the parties (including when the initiating party selects a certified IDR entity and the other party does not object), or by the Secretary under paragraph (c)(1)(iv) of this section, the certified IDR entity must review the selection and attest that it meets the requirements of paragraph (c)(1)(ii) of this section. If the certified IDR entity is unable to attest that it meets the requirements of paragraph (c)(1)(ii) of this section within 3 business days of selection, the parties, upon notification, must select another certified IDR entity under paragraph (c)(1) of this section, treating the date of notification of the failure to attest to the requirements of (c)(1)(ii) as the date of initiation of the Federal IDR process for purposes of the time periods in paragraphs (c)(1)(i) and (iv) of this section. Additionally, the certified IDR entity selected must review the information submitted in the notice of IDR initiation to determine whether the Federal IDR process applies. If the Federal IDR process does not apply, the certified IDR entity must notify the Secretary and the parties within 3 business days of making that determination.

(2) *Authority to continue negotiations*—(i) *In general.* If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing the notice of

IDR initiation to the Secretary consistent with paragraph (b)(2) of this section, but before the certified IDR entity has made its payment determination, the amount agreed to by the parties for the qualified IDR item or service will be treated as the out-of-network rate for the qualified IDR item or service. To the extent the amount exceeds the initial payment amount (or initial denial of payment) and any cost sharing paid or required to be paid by the participant or beneficiary, payment must be made directly by the plan or issuer to the nonparticipating provider, facility, or nonparticipating provider of air ambulance services not later than 30 business days after the agreement is reached. In no instance may either party seek additional payment from the participant or beneficiary, including in instances in which the out-of-network rate exceeds the qualifying payment amount. The initiating party must send a notification to the Secretary and to the certified IDR entity (if selected) electronically, through the Federal IDR portal, as soon as possible, but no later than 3 business days after the date of the agreement. The notification must include the out-of-network rate for the qualified IDR item or service and signatures from authorized signatories for both parties.

(ii) *Method of allocation of the certified IDR entity fee.* In the case of an agreement described in paragraph (c)(2)(i) of this section, the certified IDR entity is required to return half of each parties' certified IDR entity fee, unless directed otherwise by both parties. The administrative fee under paragraph (d)(2) of this section will not be returned to the parties.

(3) *Treatment of batched items and services*—(i) *In general.* Batched items and services may be submitted and considered jointly as part of one payment determination by a certified IDR entity only if the batched items and services meet the requirements of this paragraph (c)(3)(i). Batched items and services submitted and considered jointly as part of one payment determination under this paragraph (c)(3)(i) are treated as a batched determination and subject to the fee for batched determinations under this section.

(A) The qualified IDR items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services. Items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services if the items or services are billed with the same National Provider Identifier or Tax Identification Number;

(B) Payment for the qualified IDR items and services would be made by the same plan or issuer;

(C) The qualified IDR items and services are the same or similar items and services. The qualified IDR items and services are considered to be the same or similar items or services if each is billed under the same service code, or a comparable code under a different procedural code system, such as Current Procedural Terminology (CPT) codes with modifiers, if applicable, Healthcare Common Procedure Coding System (HCPCS) with modifiers, if applicable, or Diagnosis-Related Group (DRG) codes with modifiers, if applicable; and

(D) All the qualified IDR items and services were furnished within the same 30-business-day period, or the same 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, as applicable.

(ii) *Treatment of bundled payment arrangements.* In the case of qualified IDR items and services billed by a provider, facility, or provider of air ambulance services as part of a bundled payment arrangement, or where a plan or issuer makes or denies an initial payment as a bundled payment, the qualified IDR items and services may be submitted as part of one payment determination. Bundled payment arrangements submitted under this paragraph (c)(3)(ii) are subject to the rules for batched determinations and the certified IDR entity fee for single determinations.

(4) *Payment determination for a qualified IDR item or service*—(i) *Submission of offers.* Not later than 10 business days after the selection of the certified IDR entity, the plan or issuer and the provider, facility, or provider of air ambulance services:

(A) Must each submit to the certified IDR entity:

(*1*) An offer of an out-of-network rate expressed as both a dollar amount and the corresponding percentage of the qualifying payment amount represented by that dollar amount;

(*2*) Information requested by the certified IDR entity relating to the offer.

(*3*) The following additional information, as applicable—

(*i*) For providers and facilities, information on the size of the provider's practice or of the facility (if applicable). Specifically, a group of providers must specify whether the providers' practice has fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. For facilities, the facility must specify whether the facility has 50 or fewer employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees;

(*ii*) For providers and facilities, information on the practice specialty or type, respectively (if applicable);

(*iii*) For plans and issuers, information on the coverage area of the plan or issuer, the relevant geographic region for purposes of the qualifying payment amount, whether the coverage is fully-insured or partially or fully self-insured (or a FEHB carrier if the item or service relates to FEHB plans); and

(*iv*) The qualifying payment amount for the applicable year for the same or similar item or service as the qualified IDR item or service.

(B) May each submit to the certified IDR entity any information relating to the offer that was submitted by either party, except that the information may not include information on factors described in paragraph (c)(4)(v) of this section.

(ii) *Payment determination and notification.* Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must:

(A) Select as the out-of-network rate for the qualified IDR item or service one of the offers submitted under paragraph (c)(4)(i) of this section, weighing only the considerations specified in paragraph (c)(4)(iii) of this section (as applied to the information provided by the parties pursuant to paragraph (c)(4)(i) of this section). The certified IDR entity must select the offer that the certified IDR entity determines best represents the value of the qualified IDR item or service as the out-of-network rate.

(B) Notify the plan or issuer and the provider or facility, as applicable, of the selection of the offer under paragraph (c)(4)(ii)(A) of this section, and provide the written decision required under (c)(4)(vi) of this section.

(iii) *Considerations in determination.* In determining which offer to select:

(A) The certified IDR entity must consider the qualifying payment amount(s) for the applicable year for the same or similar item or service.

(B) The certified IDR entity must then consider information submitted by a party that relates to the following circumstances:

(*1*) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished the qualified IDR item or service (such as those endorsed by the consensus-based entity authorized in section 1890 of the Social Security Act).

(*2*) The market share held by the provider or facility or that of the plan or issuer in the geographic region in which the qualified IDR item or service was provided.

(*3*) The acuity of the participant, beneficiary, or enrollee receiving the qualified IDR item or service, or the complexity of furnishing the qualified IDR item or service to the participant, beneficiary, or enrollee.

(*4*) The teaching status, case mix, and scope of services of the facility that furnished the qualified IDR item or service, if applicable.

(*5*) Demonstration of good faith efforts (or lack thereof) made by the provider or facility or the plan or issuer to enter into network agreements with each other, and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous 4 plan years.

(C) The certified IDR entity must also consider information provided by a party in response to a request by the certified IDR entity under paragraph (c)(4)(i)(A)(*2*) of this section that relates to the offer for the payment amount for the qualified IDR item or

service that is the subject of the payment determination and that does not include information on factors described in paragraph (c)(4)(v) of this section.

(D) The certified IDR entity must also consider additional information submitted by a party that relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination and that does not include information on factors described in paragraph (c)(4)(v) of this section.

(E) In weighing the considerations described in paragraphs (c)(4)(iii)(B) through (D) of this section, the certified IDR entity should evaluate whether the information is credible and relates to the offer submitted by either party for the payment amount for the qualified IDR item or service that is the subject of the payment determination. The certified IDR entity should not give weight to information to the extent it is not credible, it does not relate to either party's offer for the payment amount for the qualified IDR item or service, or it is already accounted for by the qualifying payment amount under paragraph (c)(4)(iii)(A) of this section or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section.

(iv) *Examples.* The rules of paragraph (c)(4)(iii) of this section are illustrated in the following paragraphs. Each example assumes that the Federal IDR process applies for purposes of determining the out-of-network rate, that both parties have submitted the information parties are required to submit as part of the Federal IDR process, and that the submitted information does not include information on factors described in paragraph (c)(4)(v) of this section:

(A) *Example 1—(1) Facts.* A level 1 trauma center that is a nonparticipating emergency facility and an issuer are parties to a payment determination in the Federal IDR process. The facility submits an offer that is higher than the qualifying payment amount. The facility also submits additional written information showing that the scope of services available at the facility was critical to the delivery of care for the qualified IDR item or service provided, given the particular patient's acuity. This information is determined to be credible by the certified IDR entity. Further, the facility submits additional information showing the contracted rates used to calculate the qualifying payment amount for the qualified IDR item or service were based on a level of service that is typical in cases in which the services are delivered by a facility that is not a level 1 trauma center and that does not have the capability to provide the scope of services provided by a level 1 trauma center. This information is also determined to be credible by the certified IDR entity. The issuer submits an offer equal to the qualifying payment amount. No additional information is submitted by either party. The certified IDR entity determines that all the information submitted by the nonparticipating emergency facility relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(A) (*Example 1*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the nonparticipating emergency facility, provided the information relates to circumstances described in paragraphs (c)(4)(iii)(B) through (D) of this section and relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination. If the certified IDR entity determines that it is appropriate to give weight to the additional credible information submitted by the nonparticipating emergency facility and that the additional credible information submitted by the facility demonstrates that the facility's offer best represents the value of the qualified IDR item or service, the certified IDR entity should select the facility's offer.

(B) *Example 2—(1) Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The provider submits an offer that is higher than the qualifying payment amount. The provider also submits additional written

information regarding the level of training and experience the provider possesses. This information is determined to be credible by the certified IDR entity, but the certified IDR entity finds that the information does not demonstrate that the provider's level of training and experience relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination (for example, the information does not show that the provider's level of training and experience was necessary for providing the qualified IDR service that is the subject of the payment determination to the particular patient, or that the training or experience made an impact on the care that was provided). The nonparticipating provider does not submit any additional information. The issuer submits an offer equal to the qualifying payment amount, with no additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(B) (*Example 2*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity must then consider the additional information submitted by the nonparticipating provider, provided the information relates to circumstances described in paragraphs (c)(4)(iii)(B) through (D) of this section and relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination. In addition, the certified IDR entity should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines that the additional information submitted by the provider is credible but does not relate to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination, and determines that the issuer's offer best represents the value of the qualified IDR service, in the absence of any other credible information that relates to either party's offer, the certified IDR entity should select the issuer's offer.

(C) *Example 3—(1) Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process involving an emergency department visit for the evaluation and management of a patient. The provider submits an offer that is higher than the qualifying payment amount. The provider also submits additional written information showing that the acuity of the patient's condition and complexity of the qualified IDR service furnished required the taking of a comprehensive history, a comprehensive examination, and medical decision making of high complexity. This information is determined to be credible by the certified IDR entity. The issuer submits an offer equal to the qualifying payment amount for CPT code 99285, which is the CPT code for an emergency department visit for the evaluation and management of a patient requiring a comprehensive history, a comprehensive examination, and medical decision making of high complexity. The issuer also submits additional written information showing that this CPT code accounts for the acuity of the patient's condition. This information is determined to be credible by the certified IDR entity. The certified IDR entity determines that the information provided by the provider and issuer relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(C) (*Example 3*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the parties, but the certified IDR entity should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines the additional information on the acuity of the patient and complexity of the service is already accounted for in the calculation of the qualifying payment amount, the certified IDR entity should not give weight to the additional information

provided by the provider. If the certified IDR entity determines that the issuer's offer best represents the value of the qualified IDR service, the certified IDR entity should select the issuer's offer.

(D) *Example 4—(1) Facts.* A nonparticipating emergency facility and an issuer are parties to a payment determination in the Federal IDR process. Although the facility is not participating in the issuer's network during the relevant plan year, it was a participating facility in the issuer's network in the previous 4 plan years. The issuer submits an offer that is higher than the qualifying payment amount and that is equal to the facility's contracted rate (adjusted for inflation) for the previous year with the issuer for the qualified IDR service. The issuer also submits additional written information showing that the contracted rates between the facility and the issuer during the previous 4 plan years were higher than the qualifying payment amount submitted by the issuer, and that these prior contracted rates account for the case mix and scope of services typically furnished at the nonparticipating facility. The certified IDR entity determines this information is credible and that it relates to the offer submitted by the issuer for the payment amount for the qualified IDR service that is the subject of the payment determination. The facility submits an offer that is higher than both the qualifying payment amount and the contracted rate (adjusted for inflation) for the previous year with the issuer for the qualified IDR service. The facility also submits additional written information, with the intent to show that the case mix and scope of services available at the facility were integral to the service provided. The certified IDR entity determines this information is credible and that it relates to the offer submitted by the facility for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(D) (*Example 4*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the parties, but should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines that the information submitted by the facility regarding the case mix and scope of services available at the facility includes information that is also accounted for in the information the issuer submitted regarding prior contracted rates, then the certified IDR entity should give weight to that information only once. The certified IDR entity also should not give weight to the same information provided by the nonparticipating emergency facility in relation to any other factor. If the certified IDR entity determines that the issuer's offer best represents the value of the qualified IDR service, the certified IDR entity should select the issuer's offer.

(E) *Example 5—(1) Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process regarding a qualified IDR service for which the issuer downcoded the service code that the provider billed. The issuer submits an offer equal to the qualifying payment amount (which was calculated using the downcoded service code). The issuer also submits additional written information that includes the documentation disclosed to the nonparticipating provider under §149.140(d)(1)(ii) at the time of the initial payment (which describes why the service code was downcoded). The certified IDR entity determines this information is credible and that it relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. The provider submits an offer equal to the amount that would have been the qualifying payment amount had the service code not been downcoded. The provider also submits additional written information that includes the documentation disclosed to the nonparticipating provider under §149.140(d)(1)(ii) at the time of

the initial payment. Further, the provider submits additional written information that explains why the billed service code was more appropriate than the downcoded service code, as evidence that the provider's offer, which is equal to the amount the qualifying payment amount would have been for the service code that the provider billed, best represents the value of the service furnished, given its complexity. The certified IDR entity determines this information to be credible and that it relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(E) (*Example 5*), the certified IDR entity must consider the qualifying payment amount, which is based on the downcoded service code. The certified IDR entity then must consider whether to give weight to additional information submitted by the parties. If the certified IDR entity determines that the additional credible information submitted by the provider demonstrates that the nonparticipating provider's offer, which is equal to the qualifying payment amount for the service code that the provider billed, best represents the value of the qualified IDR service, the certified IDR entity should select the nonparticipating provider's offer.

(v) *Prohibition on consideration of certain factors.* In determining which offer to select, the certified IDR entity must not consider:

(A) Usual and customary charges (including payment or reimbursement rates expressed as a proportion of usual and customary charges);

(B) The amount that would have been billed by the provider or facility with respect to the qualified IDR item or service had the provisions of 45 CFR 149.410 and 149.420 (as applicable) not applied; or

(C) The payment or reimbursement rate for items and services furnished by the provider or facility payable by a public payor, including under the Medicare program under title XVIII of the Social Security Act; the Medicaid program under title XIX of the Social Security Act; the Children's Health Insurance Program under title XXI of the Social Security Act; the TRICARE program under chapter 55 of title 10, United States Code; chapter 17 of title 38, United States Code; or demonstration projects under section 1115 of the Social Security Act.

(vi) *Written decision.* (A) The certified IDR entity must explain its determination in a written decision submitted to the parties and the Secretary, in a form and manner specified by the Secretary;

(B) The certified IDR entity's written decision must include an explanation of their determination, including what information the certified IDR entity determined demonstrated that the offer selected as the out-of-network rate is the offer that best represents the value of the qualified IDR item or service, including the weight given to the qualifying payment amount and any additional credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity relies on information described under paragraphs (c)(4)(iii)(B) through (D) of this section in selecting an offer, the written decision must include an explanation of why the certified IDR entity concluded that this information was not already reflected in the qualifying payment amount.

(vii) *Effects of determination*—(A) *Binding.* A determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section:

(*1*) Is binding upon the parties, in the absence of fraud or evidence of intentional misrepresentation of material facts presented to the certified IDR entity regarding the claim; and

(*2*) Is not subject to judicial review, except in a case described in any of paragraphs (1) through (4) of section 10(a) of title 9, United States Code.

(B) *Suspension of certain subsequent IDR requests.* In the case of a determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section, the party that submitted the initial notification under paragraph (b)(2) of this section may not submit a subsequent notification involving the same other party with respect to a claim for the same or similar item or service

that was the subject of the initial notification during the 90-calendar-day period following the determination.

(C) *Subsequent submission of requests permitted.* If the end of the open negotiation period specified in paragraph (b)(1) of this section occurs during the 90-calendar-day suspension period regarding claims for the same or similar item or service that were the subject of the initial notice of IDR determination as described in paragraph (c)(4)(vi) of this section, either party may initiate the Federal IDR process for those claims by submitting a notification as specified in paragraph (b)(2) of this section during the 30-business-day period beginning on the day after the last day of the 90-calendar-day suspension period.

(viii) *Recordkeeping requirements.* The certified IDR entity must maintain records of all claims and notices associated with the Federal IDR process with respect to any determination for 6 years. The certified IDR entity must make these records available for examination by the plan, issuer, FEHB carrier, provider, facility, or provider of air ambulance services, or a State or Federal oversight agency upon request, except to the extent the disclosure would violate either State or Federal privacy law.

(ix) *Payment.* If applicable, the amount of the offer selected by the certified IDR entity (less the sum of the initial payment and any cost sharing paid or owed by the participant or beneficiary) must be paid directly to the provider, facility, or provider of air ambulance services not later than 30 calendar days after the determination by the certified IDR entity. If the offer selected by the certified IDR entity is less than the sum of the initial payment and any cost sharing paid by the participant or beneficiary, the provider, facility, or provider of air ambulance services will be liable to the plan or issuer for the difference. The provider, facility, or provider of air ambulance services must pay the difference directly to the plan or issuer not later than 30 calendar days after the determination by the certified IDR entity.

(d) *Costs of IDR process*—(1) *Certified IDR entity fee.* (i) With respect to the Federal IDR process described in paragraph (c) of this section, the party whose offer submitted to the certified IDR entity under paragraph (c)(4)(ii)(A) of this section is not selected is responsible for the payment to the certified IDR entity of the predetermined fee charged by the certified IDR entity.

(ii) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must pay the predetermined certified IDR entity fee charged by the certified IDR entity to the certified IDR entity at the time the parties submit their offers under (c)(4)(i) of this section. The certified IDR entity fee paid by the prevailing party whose offer is selected by the certified IDR entity will be returned to that party within 30 business days following the date of the certified IDR entity's determination.

(2) *Administrative fee.* (i) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must, at the time the certified IDR entity is selected under paragraph (c)(1) of this section, pay to the certified IDR entity a non-refundable administrative fee due to the Secretary for participating in the Federal IDR process described in this section.

(ii) The administrative fee amount will be established in guidance published annually by the Secretary in a manner such that the total fees paid for a year are estimated to be equal to the projected amount of expenditures by the Departments of the Treasury, Labor, and Health and Human Services for the year in carrying out the Federal IDR process.

(e) *Certification of IDR entity*—(1) *In general.* In order to be selected under paragraph (c)(1) of this section—

(i) An IDR entity must meet the standards described in this paragraph (e) and be certified by the Secretary, jointly with the Secretaries of Labor and the Treasury, as set forth in this paragraph (e) of this section and guidance promulgated by the Secretary. Once certified, the IDR entity will be provided with a certified IDR entity number.

(ii) An IDR entity must provide written documentation to the Secretary regarding general company information (such as contact information, Taxpayer

Identification Number, and website), as well as the applicable service area in which the IDR entity intends to conduct payment determinations under the Federal IDR process. IDR entities may choose to submit their application for all States or self-limit to a particular subset of States.

(iii) An IDR entity that the Secretary, jointly with the Secretary of Labor and the Secretary of the Treasury, certifies must enter into an agreement as a condition of certification. The agreement shall include specified provisions encompassed by this section, including, but not limited to, the requirements applicable to certified IDR entities when making payment determinations as well as the requirements regarding certification and revocation (such as specifications for wind down activities and reallocation of certified IDR entity fees, where warranted).

(2) *Requirements.* An IDR entity must provide written documentation to the Secretary through the Federal IDR portal that demonstrates that the IDR entity satisfies the following standards to be a certified IDR entity under this paragraph (e):

(i) Possess (directly or through contracts or other arrangements) sufficient arbitration and claims administration of health care services, managed care, billing and coding, medical and legal expertise to make the payment determinations described in paragraph (c) of this section within the time prescribed in paragraph (c)(4)(ii) of this section.

(ii) Employ (directly or through contracts or other arrangements) a sufficient number of personnel to make the determinations described in paragraph (c) of this section within the time prescribed by (c)(4)(ii) of this section. To satisfy this standard, the written documentation must include a description of the IDR entity's organizational structure and capabilities, including an organizational chart and the credentials, responsibilities, and number of personnel employed to make determinations described in paragraph (c) of this section.

(iii) Maintain a current accreditation from a nationally recognized and relevant accrediting organization, such as URAC, or ensure that it otherwise possesses the requisite training to conduct payment determinations (for example, providing documentation that personnel employed by the IDR entity have completed arbitration training by the American Arbitration Association, the American Health Law Association, or a similar organization);

(iv) Have a process to ensure that no conflict of interest, as defined in paragraph (a)(2) of this section, exists between the parties and the personnel the certified IDR entity assigns to a payment determination to avoid violating paragraph (c)(1)(ii) of this section, including policies and procedures for conducting ongoing audits for conflicts of interest, to ensure that should any arise, the certified IDR entity has procedures in place to inform the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, of the conflict of interest and to mitigate the risk by reassigning the dispute to other personnel in the event that any personnel previously assigned have a conflict of interest.

(v) Have a process to maintain the confidentiality of IIHI obtained in the course of conducting determinations. A certified IDR entity's responsibility to comply with these confidentiality requirements shall survive revocation of the IDR entity's certification for any reason, and IDR entities must comply with the record retention and disposal requirements described in this section. Under this process, once certified, the certified IDR entity must comply with the following requirements:

(A) *Privacy.* The certified IDR entity may create, collect, handle, disclose, transmit, access, maintain, store, and/or use IIHI, only to perform:

(*1*) The certified IDR entity's required duties described in this section; and

(*2*) Functions related to carrying out additional obligations as may be required under applicable Federal or State laws or regulations.

(B) *Security.* (*1*) The certified IDR entity must ensure the confidentiality of all IIHI it creates, obtains, maintains, stores, and transmits;

(*2*) The certified IDR entity must protect against any reasonably anticipated threats or hazards to the security of this information;

(*3*) The certified IDR entity must ensure that IIHI is securely destroyed or disposed of in an appropriate and reasonable manner 6 years from either the date of its creation or the first date on which the certified IDR entity had access to it, whichever is earlier.

(*4*) The certified IDR entity must implement policies and procedures to prevent, detect, contain, and correct security violations in the event of a breach of IIHI;

(C) *Breach notification.* The certified IDR entity must, following the discovery of a breach of unsecured IIHI, notify of the breach the provider, facility, or provider of air ambulance services; the plan and issuer; the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor; and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach, to the extent possible.

(*1*) *Breaches treated as discovered.* For purposes of this paragraph (e)(2)(v)(C), a breach shall be treated as discovered by a certified IDR entity as of the first day on which the breach is known to the certified IDR entity or, by exercising reasonable diligence, would have been known to the certified IDR entity. A certified IDR entity shall be deemed to have knowledge of a breach if the breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach, who is an employee, officer, or other agent of the certified IDR entity;

(*2*) *Timing of notification.* A certified IDR entity must provide the notification required by this paragraph (e)(2)(v)(C) without unreasonable delay and in no case later than 60 calendar days after discovery of a breach.

(*3*) *Content of notification.* The notification required by this paragraph (e)(2)(v)(C) must include, to the extent possible:

(*i*) The identification of each individual whose unsecured IIHI has been, or is reasonably believed by the certified IDR entity to have been, subject to the breach;

(*ii*) A brief description of what happened, including the date of the breach and the date of the discovery of the breach, to the extent known;

(*iii*) A description of the types of unsecured IIHI that were involved in the breach (for example whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);

(*iv*) A brief description of what the certified IDR entity involved is doing to investigate the breach, to mitigate harm to the affected parties, and to protect against any further breaches; and

(*v*) Contact procedures for individuals to ask questions or learn additional information, which must include a toll-free telephone number, email address, website, or postal address.

(*4*) *Method for providing notification.* A certified IDR entity must submit the notification required by this paragraph (e)(2)(v)(C) in written form (in clear and understandable language) either on paper or electronically through the Federal IDR portal or electronic mail.

(D) *Application to contractor and subcontractors.* The certified IDR entity must ensure compliance with this paragraph (e)(2)(v) of this section by any contractor or subcontractor with access to IIHI performing any duties related to the Federal IDR process.

(vi) Meet appropriate indicators of fiscal integrity and stability by demonstrating that the certified IDR entity has a system of safeguards and controls in place to prevent and detect improper financial activities by its employees and agents to assure fiscal integrity and accountability for all certified IDR entity fees and administrative fees received, held, and disbursed and by submitting 3 years of financial statements or, if not available, other information to demonstrate fiscal stability of the IDR entity;

(vii) Provide a fixed fee for single determinations and a separate fixed fee for batched determinations within the upper and lower limits for each, as set forth in guidance issued by the Secretary. The certified IDR entity may not charge a fee that is not within the approved limits as set forth in guidance unless the certified IDR entity or

IDR entity seeking certification receives written approval from the Secretary to charge a flat rate beyond the upper or lower limits approved by the Secretary for fees. The certified IDR entity or IDR entity seeking certification may update its fees and seek approval from the Secretary to charge a flat fee beyond the upper or lower limits for fees, annually as provided in guidance. In order for the certified IDR entity to receive the Secretary's written approval to charge a flat fee beyond the upper or lower limits for fees as set forth in guidance, it must satisfy both conditions in paragraphs (e)(2)(v)(A) and (B) of this section, as follows:

(A) Submit, in writing, a proposal to the Secretary that includes:

(*1*) The alternative flat fee the certified IDR entity or IDR entity seeking certification believes is appropriate for the certified IDR entity or IDR entity seeking certification to charge;

(*2*) A description of the circumstances that require the alternative fee; and

(*3*) A description of how the alternative flat rate will be used to mitigate the effects of these circumstances; and

(B) Receive from the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor written approval to charge the fee documented in the certified IDR entity's or the IDR entity seeking certification's written proposal.

(viii) Have a procedure in place to retain the certified IDR entity fees described in paragraph (d)(1) of this section paid by both parties in a trust or escrow account and to return the certified IDR entity fee paid by the prevailing party of an IDR payment determination, or half of each party's certified IDR entity fee in the case of an agreement described in paragraph (c)(2)(i) of this section, within 30 business days following the date of the determination;

(ix) Have a procedure in place to retain the administrative fees described in paragraph (d)(2) of this section and to remit the administrative fees to the Secretary in accordance with the timeframe and procedures set forth in guidance published by the Secretary;

(x) Discharge its responsibilities in accordance with paragraph (c) of this section, including not making any determination with respect to which the certified IDR entity would not be eligible for selection pursuant to paragraph (c)(1) of this section; and

(xi) Collect the information required to be reported to the Secretary under paragraph (f) of this section and report the information on a timely basis in the form and manner provided in guidance published by the Secretary.

(3) Conflict-of-interest standards. In addition to the general standards set forth in paragraph (e)(2)(iv) of this section, an IDR entity must provide written documentation that the IDR entity satisfies the standards to be a certified IDR entity under this paragraph (e)(3).

(i) The IDR entity must provide an attestation indicating that it does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(ii) The IDR entity must have procedures in place to ensure that personnel assigned to a determination do not have any conflicts of interest regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b). In order to satisfy this requirement, if certified, the IDR entity must ensure that any personnel assigned to a determination do not have any conflicts of interest as defined in paragraph (a)(2) of this section.

(iii) Following certification under this paragraph (e), if a certified IDR entity acquires control of, becomes controlled by, or comes under common control with any entity described in paragraph (e)(3)(i) of this section, the certified IDR entity must notify the Secretary in writing no later than 3 business days after the acquisition or exercise of control and shall be subject to the revocation of certification under paragraph (e)(6)(ii) of this section.

(4) *Period of certification.* Subject to paragraphs (e)(5) and (6) of this section, each certification (including a recertification) of a certified IDR entity under the process described in paragraph (e)(1) of this section will be effective for a 5-year period.

(5) *Petition for denial or revocation*—(i) *In general.* An individual, provider, facility, provider of air ambulance services, plan, or issuer may petition for a denial of a certification for an IDR entity or a revocation of a certification for a certified IDR entity for failure to meet a requirement of this section using the standard form and manner set forth in guidance to be issued by the Secretary. The petition for denial of a certification must be submitted within the timeframe set forth in guidance issued by the Secretary.

(ii) *Content of petition.* The individual, provider, facility, provider of air ambulance services, plan, or issuer seeking denial or revocation of certification must submit a written petition using the standard form issued by the Secretary including the following information:

(A) The identity of the IDR entity seeking certification or certified IDR entity that is the subject of the petition;

(B) The reason(s) for the petition;

(C) Whether the petition seeks denial or revocation of a certification;

(D) Documentation to support the reasons outlined in the petition; and

(E) Other information as may be required by the Secretary.

(iii) *Process.* (A) The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor will acknowledge receipt of the petition within 10 business days of receipt of the petition.

(B) If the Secretary finds that the petition adequately shows a failure of the IDR entity seeking certification or the certified IDR entity to follow the requirements of this paragraph (e), the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will notify the IDR entity seeking certification or the certified IDR entity by providing a de-identified copy of the petition. Following the notification, the IDR entity seeking certification or certified IDR entity will have 10 business days to provide a response. After the time period for providing the response has passed, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will review the response (if any), determine whether a denial or revocation of a certification is warranted, and issue a notice of the decision to the IDR entity or certified IDR entity and to the petitioner. This decision will be subject to the appeal requirements of paragraph (e)(6)(v) of this section.

(C) Effect on certification under petition. Regarding a petition for revocation of a certified IDR entity's certification, if the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, finds that the petition adequately shows a failure to comply with the requirements of this paragraph (e), following the Secretary's notification of the failure to the certified IDR entity under paragraph (e)(5)(iii)(B) of this section, the certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations until the Secretary issues a notice of the decision to the certified IDR entity finding that a revocation of certification is not warranted.

(6) *Denial of IDR entity certification or revocation of certified IDR entity certification*—(i) *Denial of IDR entity certification.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, may deny the certification of an IDR entity under paragraph (e)(1) of this section if, during the process of certification, including as a result of a petition described in paragraph (e)(5) of this section, the Secretary determines the following:

(A) The IDR entity fails to meet the applicable standards set forth under this paragraph (e);

(B) The IDR entity has committed or participated in fraudulent or abusive activities, including, during the certification process, submitting fraudulent data, or submitting information or data the IDR entity knows to be false to the Secretary, the Secretary of the Treasury or the Secretary of Labor;

(C) The IDR entity has failed to comply with requests for information from the Secretary, the Secretary of the Treasury, or the Secretary of Labor as part of the certification process;

(D) In conducting payment determinations, including those outside the Federal IDR process, the IDR entity has failed to meet the standards that

applied to those determinations or reviews, including standards of independence and impartiality; or

(E) The IDR entity is otherwise not fit or qualified to make determinations under the Federal IDR process.

(ii) *Revocation of certification of a certified IDR entity*. The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, may revoke the certification of a certified IDR entity under paragraph (e)(1) of this section if, as a result of an audit, a petition described in paragraph (e)(5) of this section, or otherwise, the Secretary determines the following:

(A) The certified IDR entity has a pattern or practice of noncompliance with any requirements of this paragraph (e);

(B) The certified IDR entity is operating in a manner that hinders the efficient and effective administration of the Federal IDR process;

(C) The certified IDR entity no longer meets the applicable standards for certification set forth under this paragraph (e);

(D) The certified IDR entity has committed or participated in fraudulent or abusive activities, including submission of false or fraudulent data to the Secretary, the Secretary of the Treasury, or the Secretary of Labor;

(E) The certified IDR entity lacks the financial viability to provide arbitration under the Federal IDR process;

(F) The certified IDR entity has failed to comply with requests from the Secretary, the Secretary of the Treasury, or the Secretary of Labor made as part of an audit, including failing to submit all records of the certified IDR entity that pertain to its activities within the Federal IDR process; or

(G) The certified IDR entity is otherwise no longer fit or qualified to make determinations.

(iii) *Notice of denial or revocation*. The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will issue a written notice of denial to the IDR entity or revocation to the certified IDR entity within 10 business days of the Secretary's decision, including the effective date of denial or revocation, the reason(s) for denial or revocation, and the opportunity to request appeal of the denial or revocation.

(iv) *Request for appeal of denial or revocation*. To request an appeal, the IDR entity or certified IDR entity must submit a request for appeal to the Secretary within 30 business days of the date of the notice under paragraph (e)(6)(iii) of this section of denial or revocation and in the manner prescribed by the instructions to the notice. During this time period, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will not issue a notice of final denial or revocation and a certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations. If the IDR entity or certified IDR entity does not timely submit a request for appeal of the denial or revocation, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will issue a notice of final denial or revocation to the IDR entity or certified IDR entity (if applicable) and the petitioner.

(v) *Denial or final revocation*. Upon notice of denial or final revocation, the IDR entity shall not be considered a certified IDR entity and therefore shall not be eligible to accept payment determinations under the Federal IDR process. Moreover, after a notice of final revocation, the IDR entity may not re-apply to be a certified IDR entity until on or after the 181st day after the date of the notice of denial or final revocation.

(f) *Reporting of information relating to the Federal IDR process*—(1) *Reporting of information*. Within 30 business days of the close of each month, for qualified IDR items and services furnished on or after January 1, 2022, each certified IDR entity must, in a form and manner specified by the Secretary, report:

(i) The number of notices of IDR initiation submitted under paragraph (b)(2) of this section to the certified IDR entity during the immediately preceding month;

(ii) The size of the provider practices and the size of the facilities submitting notices of IDR initiation under paragraph (b)(2) of this section during the immediately preceding month, as required to be provided to the certified

IDR entity under paragraph (c)(4)(i)(A)(*2*) of this section;

(iii) The number of such notices of IDR initiation with respect to which a determination was made under paragraph (c)(4)(ii) of this section;

(iv) The number of times during the month that the out-of-network rate determined (or agreed to) under this section has exceeded the qualifying payment amount, specified by qualified IDR items and services;

(v) With respect to each notice of IDR initiation under paragraph (b)(2) of this section for which such a determination was made, the following information:

(A) A description of the qualified IDR items and services included with respect to the notification, including the relevant billing and service codes;

(B) The relevant geographic region for purposes of the qualifying payment amount for the qualified IDR items and services with respect to which the notification was provided;

(C) The amount of the offer submitted under paragraph (c)(4)(i) of this section by the plan or issuer (as applicable) and by the provider or facility (as applicable) expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under paragraph (c)(4) of this section was the offer submitted by the plan or issuer (as applicable) or by the provider or facility (as applicable);

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraphs (c)(4)(iii)(B) through (D) of this section;

(G) The practice specialty or type of each provider or facility, respectively, involved in furnishing each qualified IDR item or service;

(H) The identity for each plan or issuer, and provider or facility, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) For each determination, the number of business days elapsed between selection of the certified IDR entity and the determination of the out-of-network rate by the certified IDR entity.

(vi) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph (d)(1) of this section during the month.

(2) [Reserved]

(g) *Extension of time periods for extenuating circumstances*—(1) *General.* The time periods specified in this section (other than the time for payment, if applicable, under paragraph (c)(4)(ix) of this section) may be extended in extenuating circumstances at the Secretary's discretion if:

(i) An extension is necessary to address delays due to matters beyond the control of the parties or for good cause; and

(ii) The parties attest that prompt action will be taken to ensure that the determination under this section is made as soon as administratively practicable under the circumstances.

(2) *Process to request an extension.* The parties may request an extension by submitting a request for extension due to extenuating circumstances through the Federal IDR portal if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause.

(h) *Applicability date.* The provisions of this section are applicable with respect to plan years or in the individual market policy years beginning on or after January 1, 2022, except that the provisions regarding IDR entity certification at paragraphs (a) and (e) of this section are applicable beginning on October 7, 2021; and paragraphs (c)(4)(ii) through (iv) of this section regarding payment determinations, paragraph (c)(4)(vi)(B) of this section regarding written decisions, and paragraph (f)(1)(v)(F) of this section regarding reporting of information relating to the Federal IDR process are applicable with respect to items or services provided or furnished on or after October 25, 2022, for plan years or in the individual market policy years beginning on or after January 1, 2022.

[86 FR 56124, Oct. 7, 2021, as amended at 87 FR 52652, Aug. 26, 2022]

§ 149.520 Independent dispute resolution process for air ambulance services.

(a) *Definitions.* Unless otherwise stated, the definitions in § 149.30 apply.

(b) *Determination of out-of-network rates to be paid by health plans and health insurance issuers; independent dispute resolution process*—(1) *In general.* Except as provided in paragraphs (b)(2) and (3) of this section, in determining the out-of-network rate to be paid by group health plans and health insurance issuers offering group or individual health insurance coverage for out-of-network air ambulance services, plans and issuers must comply with the requirements of § 149.510, except that references in § 149.510 to the additional circumstances in § 149.510(c)(4)(iii)(B) shall be understood to refer to paragraph (b)(2) of this section.

(2) *Considerations for air ambulance services.* In determining which offer to select, in addition to considering the applicable qualifying payment amount(s), the certified IDR entity must consider information submitted by a party that relates to the following circumstances:

(i) The quality and outcomes measurements of the provider that furnished the services.

(ii) The acuity of the condition of the participant, beneficiary, or enrollee receiving the service, or the complexity of furnishing the service to the participant, beneficiary, or enrollee.

(iii) The training, experience, and quality of the medical personnel that furnished the air ambulance services.

(iv) Ambulance vehicle type, including the clinical capability level of the vehicle.

(v) Population density of the point of pick-up (as defined in 42 CFR 414.605) for the air ambulance (such as urban, suburban, rural, or frontier).

(vi) Demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider of air ambulance services or the plan or issuer to enter into network agreements with each other and, if applicable, contracted rates between the provider of air ambulance services and the plan or issuer, as applicable, during the previous 4 plan years.

(3) *Weighing considerations.* In weighing the considerations described in paragraph (b)(2) of this section, the certified IDR entity should evaluate whether the information is credible and relates to the offer submitted by either party for the payment amount for the qualified IDR service that is the subject of the payment determination. The certified IDR entity should not give weight to information to the extent it is not credible, it does not relate to either party's offer for the payment amount for the qualified IDR service, or it is already accounted for by the qualifying payment amount under § 149.510(c)(4)(iii)(A) or other credible information under § 149.510(c)(4)(iii)(B) through (D), except that the additional circumstances in § 149.510(c)(4)(iii)(B) shall be understood to refer to paragraph (b)(2) of this section.

(4) *Reporting of information relating to the IDR process.* In applying the requirements of § 149.510(f), within 30 business days of the close of each month, for services furnished on or after January 1, 2022, the information the certified IDR entity must report, in a form and manner specified by the Secretary, with respect to the Federal IDR process involving air ambulance services is:

(i) The number of notices of IDR initiation submitted under the Federal IDR process to the certified IDR entity that pertain to air ambulance services during the immediately preceding month;

(ii) The number of such notices of IDR initiation with respect to which a final determination was made under § 149.510(c)(4)(ii) (as applied by paragraph (b)(1) of this section);

(iii) The number of times the payment amount determined (or agreed to) under this subsection has exceeded the qualifying payment amount, specified by services;

(iv) With respect to each notice of IDR initiation under § 149.510(b)(2) of this part (as applied by paragraph (b)(1) of this section) for which a determination was made, the following information:

(A) A description of each air ambulance service included in such notification, including the relevant billing and service codes;

(B) The point of pick-up (as defined in 42 CFR 414.605) for the services included in such notification;

(C) The amount of the offers submitted under §149.510(c)(4)(i) (as applied by paragraph (b)(1) of this section) by the group health plan or health insurance issuer (as applicable) and by the nonparticipating provider of air ambulance services, expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under §149.510(c)(4)(ii) (as applied by paragraph (b)(1) of this section) to be the payment amount applied was the offer submitted by the plan or issuer (as applicable) or by the provider of air ambulance services;

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (b)(2) of this section and §149.510(c)(4)(iii)(C) and (D);

(G) Air ambulance vehicle type, including the clinical capability level of such vehicle (to the extent this information has been provided to the certified IDR entity);

(H) The identity for each plan or issuer and provider of air ambulance services, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) For each determination, the number of business days elapsed between selection of the certified IDR entity and the selection of the payment amount by the certified IDR entity.

(v) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph §149.510(d)(1) (as applied by paragraph (b)(1) of this section) during the month for determinations involving air ambulance services.

(c) *Applicability date.* The provisions of this section are applicable with respect to plan years, or in the individual market, policy years, beginning on or after January 1, 2022, except that paragraphs (b)(1), (2), and (3) and (b)(4)(iv)(F) of this section regarding payment determinations are applicable with respect to services provided or furnished on or after October 25, 2022, for plan years or in the individual market policy years beginning on or after January 1, 2022.

[86 FR 56124, Oct. 7, 2021, as amended at 87 FR 52654, Aug. 26, 2022]

Subpart G—Protection of Uninsured or Self-Pay Individuals

SOURCE: 86 FR 56134, Oct. 7, 2021, unless otherwise noted.

§ 149.610 Requirements for provision of good faith estimates of expected charges for uninsured (or self-pay) individuals.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements for health care providers and health care facilities related to the issuance of good faith estimates of expected charges for uninsured (or self-pay) individuals (or their authorized representatives), upon request or upon scheduling an item or service.

(2) *Definitions.* For purposes of this section, the following definitions apply:

(i) *Authorized representative* means an individual authorized under State law to provide consent on behalf of the uninsured (or self-pay) individual, provided that the individual is not a provider affiliated with a facility or an employee of a provider or facility represented in the good faith estimate, unless such provider or employee is a family member of the uninsured (or self-pay) individual.

(ii) *Convening health care provider or convening health care facility (convening provider or convening facility)* means the provider or facility who receives the initial request for a good faith estimate from an uninsured (or self-pay) individual and who is or, in the case of a request, would be responsible for scheduling the primary item or service.

(iii) *Co-health care provider or co-health care facility (co-provider or co-facility)* means a provider or facility other than a convening provider or a convening facility that furnishes items

or services that are customarily provided in conjunction with a primary item or service.

(iv) *Diagnosis code* means the code that describes an individual's disease, disorder, injury, or other related health conditions using the International Classification of Diseases (ICD) code set.

(v) *Expected charge* means, for an item or service, the cash pay rate or rate established by a provider or facility for an uninsured (or self-pay) individual, reflecting any discounts for such individuals, where the good faith estimate is being provided to an uninsured (or self-pay) individual; or the amount the provider or facility would expect to charge if the provider or facility intended to bill a plan or issuer directly for such item or service when the good faith estimate is being furnished to a plan or issuer.

(vi) *Good faith estimate* means a notification of expected charges for a scheduled or requested item or service, including items or services that are reasonably expected to be provided in conjunction with such scheduled or requested item or service, provided by a convening provider, convening facility, co-provider, or co-facility.

(vii) *Health care facility (facility)* means an institution (such as a hospital or hospital outpatient department, critical access hospital, ambulatory surgical center, rural health center, federally qualified health center, laboratory, or imaging center) in any State in which State or applicable local law provides for the licensing of such an institution, that is licensed as such an institution pursuant to such law or is approved by the agency of such State or locality responsible for licensing such institution as meeting the standards established for such licensing.

(viii) *Health care provider (provider)* means a physician or other health care provider who is acting within the scope of practice of that provider's license or certification under applicable State law, including a provider of air ambulance services.

(ix) *Items or services* has the meaning given in 45 CFR 147.210(a)(2).

(x) *Period of care* means the day or multiple days during which the good faith estimate for a scheduled or requested item or service (or set of scheduled or requested items or services) are furnished or are anticipated to be furnished, regardless of whether the convening provider, convening facility, co-providers, or co-facilities are furnishing such items or services, including the period of time during which any facility equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services that would not be scheduled separately by the individual, are furnished.

(xi) *Primary item or service* means the item or service to be furnished by the convening provider or convening facility that is the initial reason for the visit.

(xii) *Service code* means the code that identifies and describes an item or service using the Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), Diagnosis-Related Group (DRG) or National Drug Codes (NDC) code sets.

(xiii) *Uninsured (or self-pay) individual* means:

(A) An individual who does not have benefits for an item or service under a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code; or

(B) An individual who has benefits for such item or service under a group health plan, or individual or group health insurance coverage offered by a health insurance issuer, or a health benefits plan under chapter 89 of title 5, United States Code but who does not seek to have a claim for such item or service submitted to such plan or coverage.

(b) *Requirements of providers and facilities*—(1) *Requirements for convening providers and convening facilities.* A convening provider or convening facility must determine if an individual is an uninsured (or self-pay) individual by:

(i) Inquiring if an individual is enrolled in a group health plan, group or individual health insurance coverage offered by a health insurance issuer,

Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code;

(ii) Inquiring whether an individual who is enrolled in a group health plan, or group or individual health insurance coverage offered by a health insurance issuer or a health benefits plan under chapter 89 of title 5, United States Code is seeking to have a claim submitted for the primary item or service with such plan or coverage; and

(iii) Informing all uninsured (or self-pay) individuals of the availability of a good faith estimate of expected charges upon scheduling an item or service or upon request; information regarding the availability of good faith estimates for uninsured (or self-pay) individuals must be:

(A) Written in a clear and understandable manner, prominently displayed (and easily searchable from a public search engine) on the convening provider's or convening facility's website, in the office, and on-site where scheduling or questions about the cost of items or services occur;

(B) Orally provided when scheduling an item or service or when questions about the cost of items or services occur; and

(C) Made available in accessible formats, and in the language(s) spoken by individual(s) considering or scheduling items or services with such convening provider or convening facility.

(iv) Convening providers and convening facilities shall consider any discussion or inquiry regarding the potential costs of items or services under consideration as a request for a good faith estimate;

(v) Upon the request for a good faith estimate from an uninsured (or self-pay) individual or upon scheduling a primary item or service to be furnished for such an individual, the convening provider or convening facility must contact, no later than 1 business day of such scheduling or such request, all co-providers and co-facilities who are reasonably expected to provide items or services in conjunction with and in support of the primary item or service and request that the co-providers or co-facilities submit good faith estimate information (as specified in paragraphs (b)(2) and (c)(2) of this section) to the convening provider or facility; the request must also include the date that good faith estimate information must be received by the convening provider or facility;

(vi) Provide a good faith estimate (as specified in paragraph (c)(1) of this section) to uninsured (or self-pay) individuals within the following timeframes:

(A) When a primary item or service is scheduled at least 3 business days before the date the item or service is scheduled to be furnished: Not later than 1 business day after the date of scheduling;

(B) When a primary item or service is scheduled at least 10 business days before such item or service is scheduled to be furnished: Not later than 3 business days after the date of scheduling; or

(C) When a good faith estimate is requested by an uninsured (or self-pay) individual: Not later than 3 business days after the date of the request.

(vii) A convening provider or convening facility must provide an uninsured (or self-pay) individual who has scheduled an item or service with a new good faith estimate if a convening provider, convening facility, co-provider, or co-facility anticipates or is notified of any changes to the scope of a good faith estimate (such as anticipated changes to the expected charges, items, services, frequency, recurrences, duration, providers, or facilities) previously furnished at the time of scheduling; a new good faith estimate must be issued to the uninsured (or self-pay) individual no later than 1 business day before the items or services are scheduled to be furnished.

(viii) If any changes in expected providers or facilities represented in a good faith estimate occur less than 1 business day before the item or service is scheduled to be furnished, the replacement provider or facility must accept as its good faith estimate of expected charges the good faith estimate for the relevant items or services included in the good faith estimate for the items or services being furnished that was provided by the replaced provider or facility.

(ix) For good faith estimates provided upon request of an uninsured (or self-pay) individual, upon scheduling of the requested item or service, the convening provider or convening facility must provide the uninsured (or self-pay) individual with a new good faith estimate for the scheduled item or service within the timeframes specified in paragraphs (b)(1)(vi)(A) and (B) of this section; and

(x) A convening provider or convening facility may issue a single good faith estimate for recurring primary items or services if the following requirements are met, in addition to the requirements under this section:

(A) The good faith estimate for recurring items or services must include, in a clear and understandable manner, the expected scope of the recurring primary items or services (such as timeframes, frequency, and total number of recurring items or services); and

(B) The scope of a good faith estimate for recurring primary items or services must not exceed 12 months. If additional recurrences of furnishing such items or services are expected beyond 12 months (or as specified under paragraph (b)(vii) of this section), a convening provider or convening facility must provide an uninsured (or self-pay) individual with a new good faith estimate, and communicate such changes (such as timeframes, frequency, and total number of recurring items or services) upon delivery of the new good faith estimate to help patients understand what has changed between the initial good faith estimate and the new good faith estimate.

(2) *Requirements for co-providers and co-facilities.* (i) Co-providers and co-facilities must submit good faith estimate information (as specified in paragraph (c)(2) of this section) upon the request of the convening provider or convening facility. The co-provider or co-facility must provide, and the convening provider or convening facility must receive, the good faith estimate information no later than 1 business day after the co-provider or co-facility receives the request from the convening provider or convening facility.

(ii) Co-providers and co-facilities must notify and provide new good faith estimate information to a convening provider or convening facility if the co-provider or co-facility anticipates any changes to the scope of good faith estimate information previously submitted to a convening provider or convening facility (such as anticipated changes to the expected charges, items, services, frequency, recurrences, duration, providers, or facilities).

(iii) If any changes in the expected co-providers or co-facilities represented in a good faith estimate occur less than 1 business day before that the item or service is scheduled to be furnished, the replacement co-provider or co-facility must accept as its good faith estimate of expected charges the good faith estimate for the relevant items or services included in the good faith estimate for the item or service being furnished that was provided by the replaced provider or facility.

(iv) In the event that an uninsured (or self-pay) individual separately schedules or requests a good faith estimate from a provider or facility that would otherwise be a co-provider or co-facility, that provider or facility is considered a convening provider or convening facility for such item or service and must meet all requirements in paragraphs (b)(1) and (c)(1) of this section for issuing a good faith estimate to an uninsured (or self-pay) individual.

(c) *Content requirements of a good faith estimate issued to an uninsured (or self-pay) individual.* (1) A good faith estimate issued to an uninsured (or self-pay) individual must include:

(i) Patient name and date of birth;

(ii) Description of the primary item or service in clear and understandable language (and if applicable, the date the primary item or service is scheduled);

(iii) Itemized list of items or services, grouped by each provider or facility, reasonably expected to be furnished for the primary item or service, and items or services reasonably expected to be furnished in conjunction with the primary item or service, for that period of care including:

(A) Items or services reasonably expected to be furnished by the convening provider or convening facility for the period of care; and

(B) Items or services reasonably expected to be furnished by co-providers or co-facilities (as specified in paragraphs (b)(2) and (c)(2) of this section);

(iv) Applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service;

(v) Name, National Provider Identifier, and Tax Identification Number of each provider or facility represented in the good faith estimate, and the State(s) and office or facility location(s) where the items or services are expected to be furnished by such provider or facility;

(vi) List of items or services that the convening provider or convening facility anticipates will require separate scheduling and that are expected to occur before or following the expected period of care for the primary item or service. The good faith estimate must include a disclaimer directly above this list that includes the following information: Separate good faith estimates will be issued to an uninsured (or self-pay) individual upon scheduling or upon request of the listed items or services; notification that for items or services included in this list, information such as diagnosis codes, service codes, expected charges and provider or facility identifiers do not need to be included as that information will be provided in separate good faith estimates upon scheduling or upon request of such items or services; and include instructions for how an uninsured (or self-pay) individual can obtain good faith estimates for such items or services;

(vii) [Reserved]

(viii) A disclaimer that informs the uninsured (or self-pay) individual that there may be additional items or services the convening provider or convening facility recommends as part of the course of care that must be scheduled or requested separately and are not reflected in the good faith estimate;

(ix) A disclaimer that informs the uninsured (or self-pay) individual that the information provided in the good faith estimate is only an estimate regarding items or services reasonably expected to be furnished at the time the good faith estimate is issued to the uninsured (or self-pay) individual and that actual items, services, or charges may differ from the good faith estimate; and

(x) A disclaimer that informs the uninsured (or self-pay) individual of the uninsured (or self-pay) individual's right to initiate the patient-provider dispute resolution process if the actual billed charges are substantially in excess of the expected charges included in the good faith estimate, as specified in § 149.620; this disclaimer must include instructions for where an uninsured (or self-pay) individual can find information about how to initiate the patient-provider dispute resolution process and state that the initiation of the patient-provider dispute resolution process will not adversely affect the quality of health care services furnished to an uninsured (or self-pay) individual by a provider or facility; and

(xi) A disclaimer that the good faith estimate is not a contract and does not require the uninsured (or self-pay) individual to obtain the items or services from any of the providers or facilities identified in the good faith estimate.

(2) [Reserved]

(d) *Content Requirements for Good Faith Estimate Information Submitted by Co-Providers or Co-Facilities to Convening Providers or Convening Facilities.* (1) Good faith estimate information submitted to convening providers or convening facilities by co-providers or co-facilities for inclusion in the good faith estimate (described in paragraph (c)(1) of this section) must include:

(i) Patient name and date of birth;

(ii) Itemized list of items or services expected to be provided by the co-provider or co-facility that are reasonably expected to be furnished in conjunction with the primary item or service as part of the period of care;

(iii) Applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service;

(iv) Name, National Provider Identifiers, and Tax Identification Numbers of the co-provider or co-facility, and the State(s) and office or facility location(s) where the items or services are expected to be furnished by the co-provider or co-facility; and

(v) A disclaimer that the good faith estimate is not a contract and does not require the uninsured (or self-pay) individual to obtain the items or services from any of the co-providers or co-facilities identified in the good faith estimate.

(2) [Reserved]

(e) *Required Methods for Providing Good Faith Estimates for Uninsured (or Self-Pay) Individuals.* (1) A good faith estimate must be provided in written form either on paper or electronically, pursuant to the uninsured (or self-pay) individual's requested method of delivery, and within the timeframes described in paragraph (b) of this section. Good faith estimates provided electronically must be provided in a manner that the uninsured (or self-pay) individual can both save and print. A good faith estimate must be provided and written using clear and understandable language and in a manner calculated to be understood by the average uninsured (or self-pay) individual.

(2) To the extent that an uninsured (or self-pay) individual requests a good faith estimate in a method other than paper or electronically (for example, by phone or orally in person), the convening provider may orally inform the uninsured (or self-pay) individual of information contained in the good faith estimate using the method requested by the uninsured (or self-pay) individual; however, in order for a convening provider or convening facility to meet the requirements of this section, the convening provider or convening facility must issue the good faith estimate to the uninsured (or self-pay) individual in written form as specified in paragraph (e)(1) of this section.

(f) *Additional compliance provisions.* (1) A good faith estimate issued to uninsured (or self-pay) individual under this section is considered part of the patient's medical record and must be maintained in the same manner as a patient's medical record. Convening providers and convening facilities must provide a copy of any previously issued good faith estimate furnished within the last 6 years to an uninsured (or self-pay) individual upon the request of the uninsured (or self-pay) individual.

(2) Providers or facilities that issue good faith estimates issued under State processes that do not meet the requirements set forth in this section fail to comply with the requirements of this section.

(3) A provider or facility will not fail to comply with this section solely because, despite acting in good faith and with reasonable due diligence, the provider or facility makes an error or omission in a good faith estimate required under this section, provided that the provider or facility corrects the information as soon as practicable. If items or services are furnished before an error in a good faith estimate is addressed, the provider or facility may be subject to patient-provider dispute resolution if the actual billed charges are substantially in excess of the good faith estimate (as described in § 149.620).

(4) To the extent compliance with this section requires a provider or facility to obtain information from any other entity or individual, the provider or facility will not fail to comply with this section if it relied in good faith on the information from the other entity, unless the provider or facility knows, or reasonably should have known, that the information is incomplete or inaccurate. If the provider or facility learns that the information is incomplete or inaccurate, the provider or facility must provide corrected information to the uninsured (or self-pay) individual as soon as practicable. If items or services are furnished before an error in a good faith estimate is addressed, the provider or facility may be subject to patient-provider dispute resolution if the actual billed charges are substantially in excess of the good faith estimate (as described in § 149.620).

(g) *Applicability*—(1) *Applicability date.* The requirements of this section are applicable for good faith estimates requested on or after January 1, 2022 or for good faith estimates required to be provided in connection with items or services scheduled on or after January 1, 2022.

(2) *Applicability with other laws.* Nothing in this section alters or otherwise affects a provider's or facility's requirement to comply with other applicable State or Federal laws, including

those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access uninsured (or self-pay) individuals' information held by providers or facilities, except to the extent a state law prevents the application of this section.

§ 149.620 Requirements for the patient-provider dispute resolution process.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements for the patient-provider dispute resolution process, under which an uninsured (or self-pay) individual, with respect to eligible items or services under paragraph (b) of this section, may submit notification under paragraph (c) of this section to initiate the patient-provider dispute resolution process. This section sets forth in paragraph (d) of this section the certification requirements for a dispute resolution entity to become a Selected Dispute Resolution (SDR) entity contracted to resolve the patient-provider dispute, and the process for HHS to select SDR entities for patient-provider disputes under paragraph (e) of this section. This section sets forth in paragraph (f) the process and requirements regarding how SDR entities will determine the amount to be paid by an uninsured (or self-pay) individual to a provider or facility. This section also sets forth requirements for an administrative fee under paragraph (g) of this section and minimum requirements under paragraph (h) of this section for states that wish to establish processes for performing patient-provider dispute resolution in place of the Federal process.

(2) *Definitions.* Unless otherwise stated, the definitions in § 149.610(a)(2) apply to this section. Definitions related to confidentiality set forth in § 149.510(a)(2), including the definitions for *breach*, *individually identifiable health information (IIHI)*, and *unsecured IIHI* also apply to this section. Additionally, for purposes of this section, the following definitions apply:

(i) *Billed charge(s)* means the amount billed by a provider or facility for an item or service.

(ii) *Substantially in excess* means, with respect to the total billed charges by a provider or facility, an amount that is at least $400 more than the total amount of expected charges listed on the good faith estimate for the provider or facility.

(iii) *Total billed charge(s)* means the total of billed charges, by a provider or-facility, for all primary items or services and all other items or services furnished in conjunction with the primary items or services to an uninsured (or self-pay) individual, regardless of whether such items or services were included in the good faith estimate.

(b) *Eligibility for patient-provider dispute resolution*—(1) *In general.* In general, an item or service provided by a convening provider, convening facility, co-provider, or co-facility is eligible for the patient-provider dispute resolution process if the total billed charges (by the particular convening provider, convening facility, or co-provider or co-facility listed in the good faith estimate), are substantially in excess of the total expected charges for that specific provider or facility listed on the good faith estimate, as required under § 149.610.

(2) *Special rule for co-provider or co-facility substitution.* If a co-provider or co-facility that provided an estimate of the expected charge for an item or service in the good faith estimate is substituted for a different co-provider or co-facility, an item or service billed by the replacement co-provider or co-facility is eligible for dispute resolution if the billed charge is substantially in excess of the total expected charges included in the good faith estimate for the original co-provider or co-facility. If the replacement provider or facility provides the uninsured (or self-pay) individual with a new good faith estimate in accordance with § 149.610(b)(2), then the determination of whether an item or service billed by the replacement co-provider or co-facility is eligible for dispute resolution is based on whether the total billed charge for the replacement co-provider or co-facility is substantially in excess of the total expected charges included in the good faith estimate provided by the replacement co-provider or co-facility.

(c) *Initiation of the Patient Provider dispute resolution process*—(1) *In general.* With respect to an item or service that meets the requirements in paragraph (b) of this section, an uninsured (or self-pay) individual (or their authorized representative, excluding any providers directly represented in the good faith estimate, providers associated with these providers, non-clinical staff associated with these providers, or individuals employed or associated with a facility that had included services in the good faith estimate) may initiate the patient-provider dispute resolution process by submitting a notification (initiation notice) to HHS as specified in paragraph (c)(2) of this section postmarked within 120 calendar days of receiving the initial bill containing charges for the item or service that is substantially in excess of the expected charges in the good faith estimate. In addition, the uninsured (or self-pay) individual must submit an administrative fee as described in paragraph (g) of this section to the SDR entity in an amount and in a manner that will be clarified in guidance by HHS.

(2) *Initiation notice*—(i) *Content.* The notice to initiate the patient-provider dispute resolution process must include:

(A) Information sufficient to identify the item or service under dispute, including the date the item or service was provided, and a description of the item or service;

(B) A copy of the provider or facility bill for the item and service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable);

(C) A copy of the good faith estimate for the item or service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable);

(D) If not included on the good faith estimate, contact information of the provider or facility involved, including, if available, name, email address, phone number, and mailing address;

(E) The State where the items or services in dispute were furnished; and

(F) The uninsured (or self-pay) individual's communication preference, through the Federal IDR portal, or electronic or paper mail.

(ii) *Manner.* The uninsured (or self-pay) individual or their authorized representative must submit the initiation notice, to the Secretary by submitting the notice via the Federal IDR portal, electronically, or on paper, in the form and manner specified by the Secretary. The date of initiation of the patient-provider dispute resolution process will be the date the Secretary receives such initiation notice. In addition, the uninsured (or self-pay) individual must submit an administrative fee as described in paragraph (g) of this section to the SDR entity in an amount and in a manner that will be clarified in guidance by HHS.

(3) *Notification of SDR entity receipt.* Upon receipt of the initiation notice described in paragraph (c)(1) of this section, HHS will select an SDR entity according to the process described in paragraph (e) of this section. Upon selection, the SDR entity will, through the Federal IDR portal, or electronic or paper mail, notify the uninsured (or self-pay) individual, and the provider or facility that a patient-provider dispute resolution request has been received and is under review. Such notice shall also include:

(i) Sufficient information to identify the item or service under dispute;

(ii) The date the initiation notice was received;

(iii) Notice of the additional requirements for providers or facilities specified in paragraphs (c)(5) and (6) of this section while the patient-provider dispute resolution process is pending; and

(iv) Information to the uninsured (or self-pay) individual about the availability of consumer assistance resources that can assist the individual with the dispute.

(4) *Validation of initiation notice.* After the selection of the SDR entity, as described in paragraph (c)(2) of this section, the SDR entity shall review the initiation notice to ensure the items or services in dispute meet the eligibility criteria described in paragraph (b) of this section and the initiation notice contains the required information described in paragraph (c)(2). The SDR entity will notify the uninsured (or self-pay) individual of the outcome of the review, including, if applicable,

providing the individual with 21 calendar days to submit supplemental information when the initiation notice is determined to be incomplete or the items or services are determined ineligible for dispute resolution.

(i) If the SDR entity determines that the item or service meets the eligibility criteria, and the initiation notice contains the required information, the SDR entity will notify the uninsured (or self-pay) individual and the provider or facility that the that the item or service has been determined eligible for dispute resolution. The SDR entity shall request the provider or facility provide the information described in paragraph (f)(2) of this section within 10 business days.

(ii) If the SDR entity determines that the item or service does not meet the eligibility criteria or that the initiation notice does not contain the required information, the SDR entity will provide an insufficiency notice to the uninsured (or self-pay) individual of the determination and the reasons for the determination and will notify the uninsured (or self-pay) individual that the individual may submit supplemental information, postmarked within 21 calendar days, to resolve any deficiencies identified. If the insufficiency notice is not made available to an individual in a format that is accessible to individuals with disabilities or with low-English proficiency within 14 calendar days of such a request from the individual, a 14-calendar-day extension will be granted so that the individual will have a total of 35 calendar days to submit supplemental information.

(5) *Prohibitions on collections.* While the patient-provider dispute resolution process is pending, the provider or facility must not move the bill for the disputed item or service into collection or threaten to do so, or if the bill has already moved into collection, the provider or facility should cease collection efforts. The provider or facility must also suspend the accrual of any late fees on unpaid bill amounts until after the dispute resolution process has concluded.

(6) *Prohibitions on retributive action.* The provider or facility must not take or threaten to take any retributive action against an uninsured (or self-pay) individual for utilizing the patient-provider dispute resolution process to seek resolution for a disputed item or service.

(d) *Certification of SDR entities*—(1) *In general.* The Secretary shall contract with and certify only that number of SDR entities the Secretary believes will be necessary to timely resolve the volume of patient-provider disputes. As part of the contract process with HHS, a potential SDR entity must satisfy the Federal IDR entity certification criteria specified in §149.510(e), subject to the exceptions set forth in paragraphs (d)(2) of this section. In addition, the SDR entity must also meet the conflict-of-interest mitigation policy requirements specified in paragraph (d)(3) of this section. Through this contract process, HHS will assess the dispute resolution entity for compliance with all applicable SDR entity certification requirements.

(2) *Exception for SDR entity certification.* With respect to certified IDR entity requirements that do not apply to an SDR entity, potential SDR entities are not required to make the following submissions:

(i) Information regarding the service area(s) for which the entity will arbitrate cases, however, a potential SDR entity will need to submit information on their ability to operate nationwide through the contract process;

(ii) Fee schedule for batched and nonbatched claims;

(iii) Policies and procedures to hold dispute resolution entity fees in a trust or escrow account, however, a potential SDR entity must submit policies and procedures to hold administrative fees, as described in paragraph (g) of this section, and remit them to HHS in a manner specified by HHS.

(3) *Conflict of interest mitigation policies.* A potential SDR entity must also provide additional information on the SDR entity's conflict-of-interest policies and procedures, including outlining a mitigation plan in the event of an entity-level conflict of interest, under which no dispute resolution personnel affiliated with the SDR entity can fairly and impartially adjudicate a case, in compliance with the standards

in Federal Acquisition Regulation-subpart 9.5 (48 CFR subpart 9.5). Such conflict of interest mitigation plan could include utilizing a subcontractor without a conflict of interest that meets SDR entity requirements to conduct the patient-provider dispute resolution for the case.

(e) *Selection of an SDR entity*. (1) After the Secretary has received the initiation notice as described in paragraph (c) of this section, the Secretary will assign an SDR entity that is certified and contracted under paragraph (d) of this section to conduct the dispute resolution process for the item or service. Upon receiving an assignment from the Secretary to make a determination for an item or service as described in paragraph (c)(3) of this section, the SDR entity shall ensure that no conflict of interest exists, and in such case, shall notify the uninsured (or self-pay) individual and the provider or facility of the selection of the SDR entity.

(2) Should a conflict of interest exist, the SDR entity must submit notice to the Secretary of such conflict no later than 3 business days following selection by the Secretary. The Secretary will then automatically select a new SDR entity to conduct the patient-provider dispute resolution process for the item or service. In the event that no SDR entities are available to resolve the dispute, the initially-selected SDR entity will be required to initiate their entity-level conflict of interest mitigation plan as described in paragraph (d)(3) of this section. If no other contracted SDR entity, and no subcontracted entity, is able to provide the patient-provider dispute resolution services due to conflicts of interest that cannot be sufficiently mitigated or any other reason, HHS may seek to contract with an additional SDR entity as needed. In the event that HHS needs to contract with an additional SDR entity, the time periods specified in this section may be extended at HHS' discretion to allow for HHS to contract with that SDR entity.

(3) Conflict of interest means, with respect to a party to a payment determination, or SDR entity, a material relationship, status, or condition of the party, or SDR entity that impacts the ability of the SDR entity to make an unbiased and impartial payment determination. For purposes of this section, a conflict of interest exists when an SDR entity is:

(i) A provider or a facility;

(ii) An affiliate or a subsidiary of a provider or facility;

(iii) An affiliate or subsidiary of a professional or trade association representing a provider or facility; or

(iv) An SDR entity, or any personnel assigned to a determination has a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the provider, the provider's group or practice association, or the facility that is a party to the dispute.

(4) Either party to the dispute resolution process (the uninsured (or self-pay) individual, or the provider or facility) may attest that a conflict of interest exists in relation to the SDR entity assigned to a payment dispute, in which case the SDR entity must notify the Secretary of HHS no later than 3 business days receiving the attestation.

(f) *Payment determination for Patient-Provider dispute resolution*—(1) *Determination of payment amount through settlement*—(i) *In general*. If the parties to a dispute resolution process agree on a payment amount (through either an offer of financial assistance or an offer of a lower amount, or an agreement by the uninsured (or self-pay) individual to pay the billed charges in full) after the dispute resolution process has been initiated but before the date on which a determination is made under paragraph (f)(3) of this section, the provider or facility will notify the SDR entity through the Federal IDR Portal, electronically, or in paper form as soon as possible, but no later than 3 business days after the date of the agreement. The settlement notification must contain at a minimum, the settlement amount, the date of such settlement, and documentation demonstrating that the provider or facility and uninsured (or self-pay) individual have agreed to the settlement. The settlement notice must also document that the provider or facility has applied a reduction to the uninsured (or self-pay) individual's

settlement amount equal to at least half the amount of the administrative fee paid as set forth in paragraph (g) of this section. Once the SDR entity receives the settlement notice, the SDR entity shall close the dispute resolution case as settled and the agreed upon payment amount will apply for the items or services.

(ii) *Treatment of payments made prior to determination.* Payment of the billed charges (or a portion of the billed charges) by the uninsured (or self-pay) individual (or by another party on behalf of the uninsured (or self-pay) individual) prior to a determination under paragraph (f)(3) of this section does not demonstrate agreement by the uninsured (or self-pay) individual to settle at that amount or any other amount.

(2) *Determination of payment amount through the patient-provider dispute resolution process*—(i) *In general.* With respect to an item or service to which an agreement described in paragraph (f)(1) of this section does not apply, not later than 10 business days after the receipt of the selection notice from the SDR entity described in paragraph (c)(4)(i) of this section, the provider or facility must submit to the SDR entity:

(A) A copy of the good faith estimate provided to the uninsured (or self-pay) individual for the item or service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable);

(B) A copy of the billed charges provided to the uninsured (or self-pay) individual for the item or service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable); and

(C) If available, documentation demonstrating that the difference between the billed charge and the expected charges in the good faith estimate reflects the cost of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided.

(ii) *Timeframe for SDR entity determination.* Not later than 30 business days after receipt of the information described in paragraph (f)(2)(i) of this section, the SDR entity must make a determination regarding the amount to be paid by such uninsured (or self-pay) individual, taking into account the requirements in paragraph (f)(3) of this section.

(3) *Payment determination by an SDR entity*—(i) *In general.* The SDR entity must review any documentation submitted by the uninsured (or self-pay) individual, and the provider or the facility, and make a separate determination for each unique item or service charged as to whether the provider or facility has provided credible information to demonstrate that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided.

(ii) *Definition of credible information.* Credible information means information that upon critical analysis is worthy of belief and is trustworthy.

(iii) *Payment determination process.* (A) For an item or service that appears on the good faith estimate:

(*1*) If the billed charge is equal to or less than the expected charge for the item or service in the good faith estimate, the SDR entity must determine the amount to be paid for the item or service as the billed charge.

(*2*) If the billed charge for the item or service is greater than the expected charge in the good faith estimate, and the SDR entity determines that information submitted by the provider or facility does not provide credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must determine the amount to be paid for the item or service to be equal to the expected charge for the item or service in the good faith estimate.

(*3*) If the billed charge for the item or service is greater than the expected charge in the good faith estimate, and

the SDR entity determines that information submitted by the provider or facility provides credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must determine as the amount to be paid for the item or service, the lesser of:

(*i*) The billed charge; or

(*ii*) The median payment amount paid by a plan or issuer for the same or similar service, by a same or similar provider in the geographic area as defined in §149.140(a)(7) where the services were provided, that is reflected in an independent database as defined in §149.140(a)(3) using the methodology described in §149.140(c)(3), except that in cases where the amount determined by an independent database is determined to be less than the expected charge for the item or service listed on the good faith estimate, the amount to be paid will equal to the expected charge for the item or service listed on the good faith estimate. When comparing the billed charge with the amount contained in an independent database, the SDR entity should account for any discounts offered by the provider or facility.

(B) For an item or service that does not appear on the good faith estimate (new item or service):

(*1*) If the SDR entity determines that the information submitted by the provider or facility does not provide credible information that the billed charge for the new item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, then the SDR entity must determine that amount to be paid for the new item or service to be equal to $0.

(*2*) If the SDR entity determines that the information submitted by the provider or facility provides credible information that the billed charge for the new item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must select as the amount to be paid for the new item or service, the lesser of:

(*i*) The billed charge; or

(*ii*) The median payment amount paid by a plan or issuer for the same or similar service, by a same or similar provider in the geographic area as defined in §149.140(a)(7) where the services were provided, that is reflected in an independent database as defined in §149.140(a)(3) using the methodology described in §149.140(c)(3). When comparing the billed charge with the amounts contained in an independent database, the SDR entity should account for any discounts offered by the provider or facility.

(C) To calculate the final payment determination amount, the SDR entity must add together the amounts to be paid for all items or services subject to the determination. In cases where the final amount determined by the SDR entity is lower than the billed charges, the SDR entity must reduce the total amount determined by the amount paid by the individual for the administrative fee described in paragraph (g) of this section to calculate the final payment determination amount to be paid by the individual for the items or services. Once the final payment determination amount has been calculated, the SDR entity will inform the uninsured (or self-pay) individual and the provider or facility, through the Federal IDR portal, or by electronic or paper mail, of such determination, the determination amount and the SDR entity's justification for making the determination. After such notification is made, the SDR entity will close the case.

(4) *Effects of determination.* A determination made by an SDR entity under this paragraph (f) will be binding upon the parties involved, in the absence of a fraud or evidence of misrepresentation of facts presented to the selected SDR entity regarding the claim, except

that the provider or facility may provide financial assistance or agree to an offer for a lower payment amount than the SDR entity's determination, the uninsured (or self-pay) individual may agree to pay the billed charges in full, or the uninsured (or self-pay) individual and the provider or facility may agree to a different payment amount.

(g) *Costs of patient-provider dispute resolution process*—(1) *Administrative fee to participate in the patient-provider dispute resolution process.* (i) The uninsured (or self-pay) individual shall pay to the SDR entity the administrative fee amount described in section (g)(2) of this section at the initiation of the patient-provider dispute resolution process described in paragraph (c) of this section. The SDR entity shall remit all administrative fees collected to the Secretary upon receiving an invoice from HHS.

(ii) In cases where the SDR entity issues a determination and the provider or facility is the non-prevailing party as described in section (g)(1)(iv) of this section, the provider or facility must pay an amount equal to the administrative fee to the uninsured (or self-pay) individual in the form of a reduction in the payment amount that is applied by the SDR entity to the final payment determination amount as described in paragraph (f)(3) of this section.

(iii) If the SDR entity issues a determination and the provider or facility is the prevailing party as described in paragraph (g)(1)(iv) of this section, the provider or facility is not required to pay an amount equal to the administrative fee to the uninsured (or self-pay) individual in the form of a reduction in the payment amount that is applied by the SDR entity to the final payment determination amount as described in paragraph (f)(3) of this section.

(iv) For purposes of paragraphs (g)(1)(ii) and (iii) of this section, the prevailing party is the provider or facility in cases where the SDR entity determines the amount to be paid as equal to the billed charges; and the prevailing party is the uninsured (or self-pay) individual in cases where the SDR entity determines the-amount to be paid as less than the billed charges.

(v) Allocation of administrative fee in the case of settlement. In case of a settlement described in paragraph (f)(1) of this section, the provider or facility must pay an amount equal to half of the administrative fee to the uninsured (or self-pay) individual in the form of a reduction in the payment amount that is applied to the final settlement amount. The provider or facility will document in the settlement notice described in paragraph (f)(1) that it has applied a payment reduction of at least half of the administrative fee amount to the uninsured (or self-pay) individual's settlement amount.

(2) Establishment of the administrative fee. The amount of the administrative fee described in paragraph (g)(1) of this section will be specified by the Secretary through guidance.

(h) *Deferral to State patient-provider dispute resolution processes*—(1) *In general.* If the Secretary determines that a-state law provides a process to determine the amount to be paid by an uninsured (or self-pay) individual to a provider or facility, and that such process meets or exceeds the requirements in paragraph (h)(2) of this section, the Secretary shall defer to the State process and direct any patient-provider dispute resolution requests received from uninsured (or self-pay) individuals in such state to the State process to adjudicate the dispute resolution initiation request.

(2) *Minimum Federal requirements.* A State process described in paragraph (h)(1) of this section shall at a minimum:

(i) Be binding, unless the provider or facility offer for the uninsured (or self-pay) individual to pay a lower payment amount than the determination amount;

(ii) Take into consideration a good faith estimate, that meets the minimum standards established in §149.160, provided by the provider or facility to the uninsured (or self-pay) individual;

(iii) If the State has a fee charged to uninsured (or self-pay) individuals to participate in the patient-provider dispute resolution process, the fee must be equal to or less than the Federal administrative fee-established in paragraph (g) of this section; and

(iv) Have in place conflict-of-interest standards that at a minimum meets the requirements set forth in paragraphs (d) and (e) of this section.

(3) *HHS determination of State process.* HHS will review the State process to determine whether it meets or exceeds the minimum Federal requirements set forth in paragraph (h)(2) of this section—HHS will communicate with the state and determine whether such process meets or exceeds such requirements. HHS will notify the state in writing of such determination.

(4) *HHS review of State process.* HHS will review changes to the State process on an annual basis (or at other times if HHS receives information from the state that would indicate the state process no longer meets the minimum Federal requirements) to ensure the state process continues to meet or exceed the minimum Federal standards set forth in this section.

(5) *State process termination.* In the event that the State process is terminated, or HHS determines that the State process no longer meets the minimum Federal requirements described in paragraph (h)(2) of this section, HHS will make the Federal process available to uninsured (or self-pay) individuals in that State to ensure that the state's residents have access to a patient-provider dispute resolution process that meets the minimum Federal requirements.

(i) *Extension of time periods for extenuating circumstances*—(1) *In general.* The time periods specified in this section (other than the time for payment of the administrative fees under paragraph (d)(2) of this section) may be extended in extenuating circumstances at the Secretary's discretion if:

(i) An extension is necessary to address delays due to matters beyond the control of the parties or for good cause; and

(ii) The parties attest that prompt action will be taken to ensure that the determination under this section is made as soon as administratively practicable under the circumstances.

(2) *Process to request an extension.* The time periods specified in this section may be extended in the case of extenuating circumstances at HHS' discretion. The parties may request an extension by submitting a request for extension due to extenuating circumstances through the Federal IDR portal, or electronic or paper mail if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause.

(j) *Applicability date.* The provisions of this section are applicable to uninsured (or self-pay) individuals; providers (including providers of air ambulance services) and facilities; and SDR entities, generally beginning on or after January 1, 2022. The provisions regarding SDR entity certification in paragraphs (a) and (d) of this section, are applicable beginning on October 7, 2021.

Subpart H—Prescription Drug and Health Care Spending

SOURCE: 86 FR 66702, Nov. 23, 2021, unless otherwise noted.

§ 149.710 Definitions.

For purposes of this subpart, the following definitions apply in addition to the definitions in § 149.30:

Brand prescription drug means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)), or under section 351 of the PHS Act (42 U.S.C. 262), and that is generally marketed under a proprietary, trademark-protected name. The term ''brand prescription drug'' includes a drug with Emergency Use Authorization issued pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), and that is generally marketed under a proprietary, trademark-protected name. The term ''brand prescription drug'' includes drugs that the U.S. Food and Drug Administration determines to be interchangeable biosimilar products under sections 351(i)(3) and 351(k)(4) of the PHS Act (42 U.S.C. 262).

Dosage unit means the smallest form in which a pharmaceutical product is administered or dispensed, such as a pill, tablet, capsule, ampule, or measurement of grams or milliliters.

Enrollee means an individual who is enrolled, within the meaning of § 144.103 of this subchapter, in group health insurance coverage, or an individual who

is covered by individual health insurance coverage, at any time during the reference year, and includes dependents.

Federal Employees Health Benefits (FEHB) line of business refers to all health benefit plans that are offered to eligible enrollees pursuant to a contract between the Office of Personnel Management and Federal Employees Health Benefits (FEHB) Program carriers. Such plans are Federal governmental plans offered pursuant to 5 U.S.C. chapter 89.

Life-years means the total number of months of coverage for participants and beneficiaries, or for enrollees, as applicable, divided by 12.

Market segment means one of the following: The individual market (excluding the student market), the student market, the fully-insured small group market, the fully-insured large group market (excluding the FEHB line of business), self-funded plans offered by small employers, self-funded plans offered by large employers, and the FEHB line of business.

Premium amount means, with respect to individual health insurance coverage and fully-insured group health plans, earned premium as that term is defined in §158.130 of this subchapter, excluding the adjustments specified in §158.130(b)(5). Premium amount means, with respect to self-funded group health plans and other arrangements that do not rely exclusively or primarily on payments of premiums as defined in §158.130 of this subchapter, the premium equivalent amount representing the total cost of providing and maintaining coverage, including claims costs, administrative costs, and stop-loss premiums, as applicable.

Prescription drug (drug) means a set of pharmaceutical products that have been assigned a National Drug Code (NDC) by the Food and Drug Administration and are grouped by name and ingredient in the manner specified by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor.

Prescription drug rebates, fees, and other remuneration means all remuneration received by or on behalf of a plan or issuer, its administrator or service provider, including remuneration received by and on behalf of entities providing pharmacy benefit management services to the plan or issuer, with respect to prescription drugs prescribed to participants, beneficiaries, or enrollees in the plan or coverage, as applicable, regardless of the source of the remuneration (for example, pharmaceutical manufacturer, wholesaler, retail pharmacy, or vendor). Prescription drug rebates, fees, and other remuneration also include, for example, discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits. Prescription drug rebates, fees, and other remuneration include bona fide service fees. Bona fide service fees mean fees paid by a drug manufacturer to an entity providing pharmacy benefit management services to the plan or issuer that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of the entity, whether or not the entity takes title to the drug.

Reference year means the calendar year immediately preceding the calendar year in which data submissions under this section are required.

Reporting entity means an entity that submits some or all of the information required under this subpart with respect to a plan or issuer, and that may be different from the plan or issuer that is subject to the requirements of this subpart.

Student market has the meaning given in §158.103 of this subchapter.

Therapeutic class means a group of pharmaceutical products that have similar mechanisms of action or treat the same types of conditions, grouped in the manner specified by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, in guidance. The Secretary may require plans and issuers to classify drugs according to a commonly available public or commercial therapeutic classification system, a therapeutic

classification system provided by the Secretary, or a combination thereof.

Total annual spending means incurred claims, as that term is defined in §158.140 of this subchapter, excluding the adjustments specified in §158.140(b)(1)(i), (b)(2)(iv), and (b)(4), and including cost sharing. With respect to prescription drugs, total annual spending is net of prescription drug rebates, fees, and other remuneration.

§ 149.720 Reporting requirements related to prescription drug and health care spending.

(a) *General requirement.* A group health plan or a health insurance issuer offering group or individual health insurance coverage must submit an annual report to the Secretary, the Secretary of the Treasury, and the Secretary of Labor, on prescription drug and health care spending, premiums, and enrollment under the plan or coverage.

(b) *Timing and form of report.* The report for the 2020 reference year must be submitted to the Secretary by December 27, 2021. Beginning with the 2021 reference year, the report for each reference year is due by June 1 of the year following the reference year. The report must be submitted in the form and manner prescribed by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor.

(c) *Transfer of business.* Issuers that acquire a line or block of business from another issuer during a reference year are responsible for submitting the information and report required by this section for the acquired business for that reference year, including for the part of the reference year that was prior to the acquisition.

(d) *Reporting entities and special rules to prevent unnecessary duplication*—(1) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan may satisfy the requirements of paragraph (a) of this section if the plan requires the health insurance issuer offering the coverage to report the information required by this section in compliance with this subpart pursuant to a written agreement. Accordingly, if a health insurance issuer and a group health plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under paragraph (a) of this section in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the reporting requirements of paragraph (a) of this section with respect to the relevant information.

(2) *Other contractual arrangements.* A group health plan or health insurance issuer offering group or individual health insurance coverage may satisfy the requirements under paragraph (a) of this section by entering into a written agreement under which one or more other parties (such as health insurance issuers, pharmacy benefit managers, third-party administrators, or other third parties) report some or all of the information required under paragraph (a) of this section in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in accordance with paragraph (a) of this section, the plan or issuer violates the reporting requirements of paragraph (a) of this section.

(e) *Applicability date.* The provisions of this section are applicable beginning December 27, 2021.

§ 149.730 Aggregate reporting.

(a) *General requirement.* A group health plan or a health insurance issuer offering group or individual health insurance coverage must submit, or arrange to be submitted, the information required in §149.740(b) separately for each State in which group health coverage or group or individual health insurance coverage was provided in connection with the group health plan or by the health insurance issuer. The report must include the experience of all plans and policies in the State during the reference year covered by the report, and must include the experience separately for each market segment as defined in §149.710.

(b) *Aggregation by reporting entity*—(1) *In general.* If a reporting entity submits data on behalf of more than one group

health plan in a State and market segment, the reporting entity may aggregate the data required in §149.740(b) for the group health plans for each market segment in the State.

(2) *Multiple reporting entities.* (i) If multiple reporting entities submit the required data related to one or more plans or issuers in a State and market segment, the data submitted by each of these reporting entities must not be aggregated at a less granular level than the aggregation level used by the reporting entity that submits the data on total annual spending on health care services, as required by §149.740(b)(4), on behalf of these plans or issuers.

(ii) The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, may specify in guidance alternative or additional aggregation methods for data submitted by multiple reporting entities, to ensure a balance between compliance burdens and a data aggregation level that facilitates the development of the biannual public report required under section 2799A–10(b) of the PHS Act.

(3) *Group health insurance coverage with dual contracts.* If a group health plan involves health insurance coverage obtained from two affiliated issuers, one providing in-network coverage only and the second providing out-of-network coverage only, the plan's out-of-network experience may be treated as if it were all related to the contract provided by the in-network issuer.

(c) *Aggregation by State.* (1) Experience with respect to each fully-insured policy must be included on the report for the State where the contract was issued, except as specified in paragraphs (c)(3) and (4) of this section.

(2) Experience with respect to each self-funded group health plan must be included on the report for the State where the plan sponsor has its principal place of business.

(3) For individual market business sold through an association, experience must be attributed to the issue State of the certificate of coverage.

(4) For health coverage provided to plans through a group trust or multiple employer welfare arrangement, the experience must be included in the report for the State where the employer (if the plan is sponsored at the individual employer level) or the association (if the association qualifies as an employer under ERISA section 3(5)) has its principal place of business or the State where the association is incorporated, in the case of an association with no principal place of business.

(d) *Applicability date.* The provisions of this section are applicable beginning December 27, 2021.

§149.740 Required information.

(a) *Information for each plan or coverage.* The report required under §149.720 must include the following information for each plan or coverage, at the plan or coverage level:

(1) The identifying information for plans, issuers, plan sponsors, and any other reporting entities.

(2) The beginning and end dates of the plan year that ended on or before the last day of the reference year.

(3) The number of participants, beneficiaries, and enrollees, as applicable, covered on the last day of the reference year.

(4) Each State in which the plan or coverage is offered.

(b) *Information for each state and market segment.* The report required under §149.720 must include the following information with respect to plans or coverage for each State and market segment for the reference year, unless otherwise specified:

(1) The 50 brand prescription drugs most frequently dispensed by pharmacies, and for each such drug, the data elements listed in paragraph (b)(5) of this section. The most frequently dispensed drugs must be determined according to total number of paid claims for prescriptions filled during the reference year for each drug.

(2) The 50 most costly prescription drugs and for each such drug, the data elements listed in paragraph (b)(5) of this section. The most costly drugs must be determined according to total annual spending on each drug.

(3) The 50 prescription drugs with the greatest increase in expenditures between the year immediately preceding the reference year and the reference year, and for each such drug: The data elements listed in paragraph (b)(5) of

this section for the year immediately preceding the reference year, and the data elements listed in paragraph (b)(5) of this section for the reference year. The drugs with the greatest increase in expenditures must be determined based on the increase in total annual spending from the year immediately preceding the reference year to the reference year. A drug must be approved for marketing or issued an Emergency Use Authorization by the Food and Drug Administration for the entirety of the year immediately preceding the reference year and for the entirety of the reference year to be included in the data submission as one of the drugs with the greatest increase in expenditures.

(4) Total annual spending on health care services by the plan or coverage and by participants, beneficiaries, and enrollees, as applicable, broken down by the type of costs, including—

(i) Hospital costs;

(ii) Health care provider and clinical service costs, for primary care and specialty care separately;

(iii) Costs for prescription drugs, separately for drugs covered by the plan's or issuer's pharmacy benefit and drugs covered by the plan's or issuer's hospital or medical benefit; and

(iv) Other medical costs, including wellness services.

(5) Prescription drug spending and utilization, including—

(i) Total annual spending by the plan or coverage;

(ii) Total annual spending by the participants, beneficiaries, and enrollees, as applicable, enrolled in the plan or coverage, as applicable;

(iii) The number of participants, beneficiaries, and enrollees, as applicable, with a paid prescription drug claim;

(iv) Total dosage units dispensed; and

(v) The number of paid claims.

(6) Premium amounts, including—

(i) Average monthly premium amount paid by employers and other plan sponsors on behalf of participants, beneficiaries, and enrollees, as applicable;

(ii) Average monthly premium amount paid by participants, beneficiaries, and enrollees, as applicable; and

(iii) Total annual premium amount and the total number of life-years.

(7) Prescription drug rebates, fees, and other remuneration, including—

(i) Total prescription drug rebates, fees, and other remuneration, and the difference between total amounts that the plan or issuer pays the entity providing pharmacy benefit management services to the plan or issuer and total amounts that such entity pays to pharmacies.

(ii) Prescription drug rebates, fees, and other remuneration, excluding bona fide service fees, broken down by the amounts passed through to the plan or issuer, the amounts passed through to participants, beneficiaries, and enrollees, as applicable, and the amounts retained by the entity providing pharmacy benefit management services to the plan or issuer; and the data elements listed in paragraph (b)(5) of this section—

(A) For each therapeutic class; and

(B) For each of the 25 prescription drugs with the greatest amount of total prescription drug rebates and other price concessions for the reference year.

(8) The method used to allocate prescription drug rebates, fees, and other remuneration, if applicable.

(9) The impact of prescription drug rebates, fees, and other remuneration on premium and cost sharing amounts.

(c) *Applicability date.* The provisions of this section are applicable beginning December 27, 2021.

PART 150—CMS ENFORCEMENT IN GROUP AND INDIVIDUAL INSURANCE MARKETS

Subpart A—General Provisions

Sec.

Subpart B—CMS Enforcement Processes for Determining Whether States Are Failing To Substantially Enforce PHS Act requirements