Pre-publication version of No Surprises Act Part I

Interim Final Rule

The Departments of Health and Human Services (HHS), Labor (DOL) and Treasury, and the Office of Personnel Management (OPM), issued a pre-publication version of an *interim final rule* (IFR) under the *Consolidated Appropriations Act, 2021* (*CAA*) on "Requirements Related to Surprise Billing; Part I."

The regulations are generally applicable for *plan years* beginning on or after January 1, 2022 for non-grandfathered and grandfathered group health plans (GHPs). The IFR is not "official" until published in the *Federal Register*, but no major changes are expected from this pre-publication version. An excerpt of just the DOL regulations is available "*here.*"

https://www.federalregister.gov/public-inspection/2021-14379/requirements-related-to-surprise-billing-part-i

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TABLE OF CONTENTS

§ 2590.716-1 Basis and scope. 1

(a) Basis. 1

(b) Scope. 1

§ 2590.716-2 Applicability. 1

(a) In general. 1

(b) Exceptions. 1

§ 2590.716-3 Definitions. 1

Cost sharing **1**

Emergency department **2**

Emergency medical condition **2**

Emergency services **2**

Health care facility **2**

Independent freestanding emergency department **2**

Nonparticipating emergency facility **2**

Nonparticipating provider **3**

Notice of denial of payment **3**

Out-of-network rate **3**

Participating emergency facility **4**

Participating health care facility **4**

Participating provider **4**

Physician or health care provider **4**

Provider of air ambulance services **4**

Same or similar item or service **4**

Service code **5**

Qualifying payment amount **5**

Recognized amount **5**

Specified State law **5**

State **6**

Treating provider **6**

Visit 6

§ 2590.716-4 Preventing surprise medical bills for emergency services. 6

(a) In general. 6

(b) Coverage requirements. 6

(c) Definitions. 8

(1) Emergency medical condition 8

(2) Emergency services 8

(i) In general. 8

(ii) Inclusion of additional services. 9

(3) To stabilize 9

(d) Applicability date. 9

§ 2590.716-5 Preventing surprise medical bills for non-emergency services performed by nonparticipating providers at certain participating facilities. 9

(a) In general. 9

(b) Items and services described. 10

(c) Coverage requirements. 10

(d) Applicability date. 11

§ 2590.716-6 Methodology for calculating qualifying payment amount. 11

(a) Definitions. 11

(1) Contracted rate 11

(2) Derived amount 11

(3) Eligible database 11

(4) Facility of the same or similar facility type 12

(5) First coverage year 12

(6) First sufficient information year 12

(7) Geographic region 13

(8) Insurance market 14

(9) Modifiers 14

(10) Newly covered item or service 14

(11) New service code 14

(12) Provider in the same or similar specialty 14

(13) Same or similar item or service 15

(14) Service code 15

(15) Sufficient information 15

(16) Qualifying payment amount 15

(17) Underlying fee schedule rate 15

(b) Methodology for calculation of median contracted rate. 16

(1) In general. *16*
(2) Calculation rules. *16*
(3) Provider specialties; facility types. *17*
(c) Methodology for calculation of the qualifying payment amount. **17**
(1) In general. *17*
(2) New plans and coverage. *20*
(3) Insufficient information; newly covered items and services. *21*
(4) New service codes. *22*
(d) Information to be shared about qualifying payment amount. **23**
(e) Certain access fees to databases. **24**
(f) Applicability date. **24**
§ 2590.716-7 Complaints process for surprise medical bills regarding group health plans and group health insurance coverage. **24**
(a) Scope and definitions. **25**
(1) Scope. *25*
(2) Definitions. *25*
(b) Complaints process. **25**
§ 2590.716-8 [Reserved] **26**
§ 2590.716-9 [Reserved] **26**
§ 2590.717-1 Preventing surprise medical bills for air ambulance services. **26**
(a) In general. **26**
(b) Coverage requirements. **27**
(c) Applicability date. **27**
§ 2590.717-2 [Reserved] **28**
§ 2590.722 Choice of health care professional. **28**
(a) Choice of health care professional **28**
(1) Designation of primary care provider *28*
(i) In general. 28
(ii) Construction. 28
(iii) Example. 28
(2) Designation of pediatrician as primary care provider *29*
(i) In general. 29
(ii) Construction. 29

(iii) Examples. 29
(i) General rights 30
(ii) Application of paragraph. 30
(iii) Construction. 31
(iv) Examples. 31
(4) Notice of right to designate a primary care provider— 32
(i) In general. 32
(ii) Timing. 33
(iii) Model language. 33
(b) Applicability date. 34

§ 2590.716-1 Basis and scope.

(a) Basis.

§§ 2590.716-1 through 2590.722 implements §§ 716-722 of ERISA.

(b) Scope.

This part establishes standards for group health plans and health insurance issuers offering group health insurance coverage with respect to surprise medical bills, transparency in health care coverage, and additional patient protections.

§ 2590.716-2 Applicability.

(a) In general.

The requirements in §§ 2590.716-4 through 2590.716-7, §2590.717-1 and § 2590.722 of this part apply to group health plans and health insurance issuers offering group health insurance coverage (including grandfathered health plans as defined in § 2590.715- 1251 of this part), except as specified in paragraph (b) of this section.

(b) Exceptions.

The requirements in §§ 2590.716-4 through 2590.716-7, § 2590.717-1, and § 2590.722 of this part do not apply to the following:

(1) Excepted benefits as described in § 2590.732 of this part.

(2) Short-term, limited-duration insurance as defined in § 2590.701-2 of this part.

(3) Health reimbursement arrangements or other account-based group health plans as described in § 2590.715-2711(d) of this part.

§ 2590.716-3 Definitions.

The definitions in part 2590 apply to §§ 2590.716-722, unless otherwise specified. In addition, for purposes of §§ 2590.716-722, 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 or beneficiary 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 § 2590.716-4(c)(1).

Emergency services
has the meaning given the term in § 2590.716-4(c)(2).

Health care facility
with respect to a group health plan or group 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 § 2590.716-4(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 § 2590.716-4(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 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 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 §§ 2590.716-4, 2590.716-5, and 2590.717-1 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 § 2560.503-1 of this chapter.

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 54.9816T-4(b)(3)(iv)(A), 54.9816T-5(c)(3), or 54.9817T-1(b)(4)(A); 29 CFR 2590.716-4(b)(3)(iv)(A), 2590.716-5(c)(3), or 2590.717-1(b)(4)(A); or 45 CFR 149.110(b)(3)(iv)(A), 149.120(c)(3), or 149.130(b)(4)(A), 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 § 2590.716-4(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 health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant or beneficiary 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 or beneficiary 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 health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant or beneficiary 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 or beneficiary 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 health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant or beneficiary 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 § 2590.716-6(a)(13).

Service code
has the meaning given the term in § 2590.716-6(a)(14).

Qualifying payment amount
has the meaning given the term in § 2590.716-6(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 § 2590.716-6 of this part), 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 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 ERISA).

A group health plan that opts into 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.

§ 2590.716-4 Preventing surprise medical bills for emergency services.

(a) In general.
If a group health plan, or a health insurance issuer offering group 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 AllPayer 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 716(c)(6) of ERISA, 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 or beneficiary 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 § 2590.701-2 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 or beneficiary 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 45 CFR 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 beginning on or after January 1, 2022.

§ 2590.716-5 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 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 or beneficiary 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 45 CFR § 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 716(c)(6) of ERISA, 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 or beneficiary 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 beginning on or after January 1, 2022.

§ 2590.716-6 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 or beneficiary in unique circumstances, does not constitute a contract.

(2) Derived amount

has the meaning given the term in § 2590.715-2715A1 of this part.

(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 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 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 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 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 § 2590.715-2711(d)(6)(i) of this part, 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 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 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 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 or beneficiary's cost-sharing liability for the item or service, when that rate is different from the contracted rate.

(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 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), 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) x (CPI-U 2020/CPI-U 2019) x (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 or beneficiary 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 or beneficiary 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 or beneficiary 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) 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 or beneficiary 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)-(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 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 or group 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 or group 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), (c)(1)(iv), or (c)(1)(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), (c)(1)(iii), or (c)(1)(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), (c)(1)(iv), or (c)(1)(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 §§ 2590.716-4, 2590.716-5, or 2590.717-1 of this part:

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

(ii) 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 or beneficiary's cost sharing); and

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

(iii) 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 (iv) 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;

(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) Applicability date.

The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022.

§ 2590.716-7 Complaints process for surprise medical bills regarding group health plans and group 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 health insurance coverage may be failing to meet the requirements under subpart D 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 subpart D 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) DOL will consider the date a complaint is filed to be the date upon which DOL 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) DOL will notify complainants, by oral or written means, of receipt of the complaint no later than 60 business days after the complaint is received. DOL 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 complaint resolution process. As part of the response, DOL 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 or beneficiaries;

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

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

(3) DOL 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 DOL. A complaint is considered processed after DOL 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, DOL 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 DOL 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; or

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

§ 2590.716-8 [Reserved]

§ 2590.716-9 [Reserved]

§ 2590.717-1 Preventing surprise medical bills for air ambulance services.

(a) In general.

If a group health plan or a health insurance issuer offering group 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 § 2590.716-6) 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—

(A) 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)(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) 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)(A) of this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section 717(b)(6) of ERISA, 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 beginning on or after January 1, 2022.

§ 2590.717-2 [Reserved]

§ 2590.722 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 health insurance coverage, requires or provides for designation by a participant or beneficiary of a participating primary care provider, then the plan or issuer must permit each participant or beneficiary to designate any participating primary care provider who is available to accept the participant or beneficiary. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant 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:

(i) 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.

(ii) 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 health insurance coverage, requires or provides for the designation of a participating primary care provider for a child by a participant or beneficiary, the plan or issuer must permit the participant or beneficiary 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:

Example 1.

(i) 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.

(ii) 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).

Example 2.

(i) Facts.

Same facts as Example 1, 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.

(ii) 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 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 or beneficiary 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 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 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 or beneficiary 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:

Example 1.

(i) 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.

(ii) 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 obtaining gynecological services.

Example 2.

(i) Facts.

Same facts as Example 1 except that A seeks gynecological services from C, an out-of-network provider.

(ii) 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.

Example 3.
(i) Facts.
Same facts as Example 1 except that the group health plan only requires B to inform A's designated primary care physician of treatment decisions.

(ii) 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).

Example 4.
(i) 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.

(ii) 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 or beneficiary 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 or beneficiary 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, or beneficiaries, 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 or beneficiary 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 beginning on or after January 1, 2022.