
29 C.F.R. § 2590.716–8

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 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 § 2590.716–3 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 section, 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 Health and Human Services 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 administrator, plan 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 Health and Human Services 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, § 2590.716-4, or 45 CFR 149.110, as applicable, for which the conditions of 45 CFR 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-T, § 2590.716-5, or 45 CFR 149.120, as applicable, for which the conditions of 45 CFR 149.420(c) through (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, § 2590.717-1, or 45 CFR 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 § 2590.716-3;

(B) With respect to which a provider or facility (as applicable) or group health plan or health insurance issuer offering group 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 Health and Human Services.

(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), § 2590.716-4(c)(2)(i), or 45 CFR 149.110(c)(2)(i), as applicable, an emergency service as defined in 26 CFR 54.9816-4T(c)(2)(ii), § 2590.716-4(c)(2)(ii), or 45 CFR 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 § 2590.716-6(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.

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