

the termination notice, unless the enrollee appeals and the IRE reverses the MA organization's decision. If the IRE's decision is delayed because the MA organization did not timely supply necessary information or records, the MA organization is liable for the costs of any additional coverage required by the delayed IRE decision. If the IRE finds that the enrollee did not receive valid notice, coverage of provider services by the MA organization continues until at least two days after valid notice has been received. Continuation of coverage is not required if the IRE determines that coverage could pose a threat to the enrollee's health or safety.

(c) *Burden of proof.* When an enrollee appeals an MA organization's decision to terminate services to an IRE, the burden of proof rests with the MA organization to demonstrate that termination of coverage is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies.

(1) To meet this burden, the MA organization must supply any and all information that an IRE requires to sustain the MA organization's termination decision, consistent with paragraph (e) of this section.

(2) The enrollee may submit evidence to be considered by an IRE in making its decision.

(3) The MA organization or an IRE may require an enrollee to authorize release to the IRE of his or her medical records, to the extent that the records are necessary for the MA organization to demonstrate the correctness of its decision or for an IRE to determine the appeal.

(d) *Procedures an IRE must follow.* (1) On the date an IRE receives the enrollee's request for an appeal, the IRE must immediately notify the MA organization and the provider that the enrollee has filed a request for a fast-track appeal, and of the MA organization's responsibility to submit documentation consistent with paragraph (e)(3) of this section.

(2) When an enrollee requests a fast-track appeal, the IRE must determine whether the provider delivered a valid notice of the termination decision, and whether a detailed notice has been pro-

vided, consistent with paragraph (e)(1) of this section.

(3) The IRE must notify CMS about each case in which it determines that improper notification occurs.

(4) Before making its decision, the IRE must solicit the enrollee's views regarding the reason(s) for termination of services as specified in the detailed written notice provided by the MA organization, or regarding any other reason that the IRE uses as the basis of its review determination.

(5) An IRE must make a decision on an appeal and notify the enrollee, the MA organization, and the provider of services, by close of business of the day after it receives the information necessary to make the decision. If the IRE does not receive the information needed to sustain an MA organization's decision to terminate services, it may make a decision on the case based on the information at hand, or it may defer its decision until it receives the necessary information. If the IRE defers its decision, coverage of the services by the MA organization would continue until the decision is made, consistent with paragraph (b) of this section, but no additional termination notice would be required.

(e) *Responsibilities of the MA organization.* (1) When an IRE notifies an MA organization that an enrollee has requested a fast-track appeal, the MA organization must send a detailed notice to the enrollee by close of business of the day of the IRE's notification. The detailed termination notice must include the following information:

(i) A specific and detailed explanation why services are either no longer reasonable and necessary or are no longer covered.

(ii) A description of any applicable Medicare coverage rule, instruction or other Medicare policy including citations, to the applicable Medicare policy rules, or the information about how the enrollee may obtain a copy of the Medicare policy from the MA organization.

(iii) Any applicable MA organization policy, contract provision, or rationale upon which the termination decision was based.

(iv) Facts specific to the enrollee and relevant to the coverage determination

that are sufficient to advise the enrollee of the applicability of the coverage rule or policy to the enrollee's case.

(v) Any other information required by CMS.

(2) Upon an enrollee's request, the MA organization must provide the enrollee a copy of, or access to, any documentation sent to the IRE by the MA organization, including records of any information provided by telephone. The MA organization may charge the enrollee a reasonable amount to cover the costs of duplicating the information for the enrollee and/or delivering the documentation to the enrollee. The MA organization must accommodate such a request by no later than close of business of the first day after the day the material is requested.

(3) Upon notification by the IRE of a fast-track appeal, the MA organization must supply any and all information, including a copy of the notice sent to the enrollee, that the IRE needs to decide on the appeal. The MA organization must supply this information as soon as possible, but no later than by close of business of the day that the IRE notifies the MA organization that an appeal has been received from the enrollee. The MA organization must make the information available by phone (with a written record made of what is transmitted in this manner) and/or in writing, as determined by the IRE.

(4) An MA organization is financially responsible for coverage of services as provided in paragraph (b) of this section, regardless of whether it has delegated responsibility for authorizing coverage or termination decisions to its providers.

(f) *Responsibilities of the provider.* If an IRE reverses an MA organization's termination decision, the provider must provide the enrollee with a new notice consistent with § 422.624(b) of this subpart.

(g) *Reconsiderations of IRE decisions.* (1) If the IRE upholds an MA organization's termination decision in whole or in part, the enrollee may request, no later than 60 days after notification that the IRE has upheld the decision that the IRE reconsider its original decision.

(2) The IRE must issue its reconsidered determination as expeditiously as the enrollee's health condition requires but no later than within 14 days of receipt of the enrollee's request for a reconsideration.

(3) If the IRE reaffirms its decision, in whole or in part, the enrollee may appeal the IRE's reconsidered determination to OMHA for an ALJ hearing, the Council, or a Federal court, as provided for under this subpart.

(4) If on reconsideration the IRE determines that coverage of provider services should terminate on a given date, the enrollee is liable for the costs of continued services after that date unless the IRE's decision is reversed on appeal. If the IRE's decision is reversed on appeal, the MA organization must reimburse the enrollee, consistent with the appealed decision, for the costs of any covered services for which the enrollee has already paid the MA organization or provider.

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REQUIREMENTS APPLICABLE TO CERTAIN INTEGRATED DUAL ELIGIBLE SPECIAL NEEDS PLANS

SOURCE: 84 FR 15835, Apr. 16, 2019, unless otherwise noted.

§ 422.629 General requirements for applicable integrated plans.

(a) *Scope.* The provisions in this section and in §§ 422.630 through 422.634 set forth requirements for unified appeals and grievance processes with which applicable integrated plans must comply. Beginning January 1, 2021, these provisions apply to an applicable integrated plan in lieu of §§ 422.564, 422.566(c) and (d), and 422.568 through 422.590, and 422.618(a) and §§ 438.404 through 438.424 of this chapter; provisions governing Part B drugs in §§ 422.568(b)(2), 422.570(d)(2), 422.572(a)(2), 422.584(d)(1), 422.590(c), and 422.590(e)(2) apply to an applicable integrated plan.

(b) *General process.* An applicable integrated plan must create integrated processes for enrollees for integrated

grievances, integrated organization determinations, and integrated reconsiderations.

(c) *State flexibilities.* A State may, at its discretion, implement standards for timeframes or notice requirements that are more protective for the enrollee than required by this section and §§ 422.630 through 422.634. The contract under § 422.107 must include any standards that differ from the standards set forth in this section.

(d) *Evidence.* The applicable integrated plan must do the following:

(1) Provide the enrollee—

(i) A reasonable opportunity, in person and in writing, to present evidence and testimony and make legal and factual arguments for integrated grievances, and integrated reconsiderations; and

(ii) Information on how evidence and testimony should be presented to the plan.

(2) Inform the enrollee of the limited time available for presenting evidence sufficiently in advance of the resolution timeframe for appeals as specified in this section if the case is being considered under an expedited timeframe for the integrated grievance or integrated reconsideration.

(e) *Assistance.* In addition to the requirements in § 422.562(a)(5), the applicable integrated plan must provide an enrollee reasonable assistance in completing forms and taking other procedural steps related to integrated grievances and integrated appeals.

(f) *Applicable requirements.* The requirements in §§ 422.560, 422.561, 422.562, 422.566, and 422.592 through 422.626 apply to an applicable integrated plan unless otherwise provided in this section or in §§ 422.630 through 422.634.

(g) *Acknowledgement.* The applicable integrated plan must send to the enrollee written acknowledgement of integrated grievances and integrated reconsiderations upon receiving the request.

(h) *Recordkeeping.* (1) The applicable integrated plan must maintain records of integrated grievances and integrated appeals. Each applicable integrated plan that is a Medicaid managed care organization must review the Medicaid-related information as part of its ongoing monitoring procedures, as well

as for updates and revisions to the State quality strategy.

(2) The record of each integrated grievance or integrated appeal must contain, at a minimum:

(i) A general description of the reason for the integrated appeal or integrated grievance.

(ii) The date of receipt.

(iii) The date of each review or, if applicable, review meeting.

(iv) Resolution at each level of the integrated appeal or integrated grievance, if applicable.

(v) Date of resolution at each level, if applicable.

(vi) Name of the enrollee for whom the integrated appeal or integrated grievance was filed.

(vii) Date the applicable integrated plan notified the enrollee of the resolution.

(3) The record of each integrated grievance or integrated appeal must be accurately maintained in a manner accessible to the State and available upon request to CMS.

(i) *Prohibition on punitive action.* Each applicable integrated plan must ensure that no punitive action is taken against a provider that requests an integrated organization determination or integrated reconsideration, or supports an enrollee's request for these actions.

(j) *Information to providers and subcontractors.* The applicable integrated plan must provide information about the integrated grievance and integrated appeal system to all providers and subcontractors at the time they enter into a contract including, at minimum, information on integrated grievance, integrated reconsideration, and fair hearing procedures and timeframes as applicable. Such information must include the following:

(1) The right to file an integrated grievance and integrated reconsideration.

(2) The requirements and timeframes for filing an integrated grievance or integrated reconsideration.

(3) The availability of assistance in the filing process.

(k) *Review decision-making requirements—*(1) *General rules.* Individuals making decisions on integrated appeals and grievances must take into account all comments, documents, records, and

other information submitted by the enrollee or their representative without regard to whether such information was submitted or considered in the initial adverse integrated organization determination.

(2) *Integrated grievances.* Individuals making decisions on integrated grievances must be individuals who—

(i) Were neither involved in any previous level of review or decision-making nor a subordinate of any such individual; and

(ii) If deciding any of the following, have the appropriate clinical expertise in treating the enrollee's condition or disease:

(A) A grievance regarding denial of expedited resolution of an appeal.

(B) A grievance that involves clinical issues.

(3) *Integrated organization determinations.* If the applicable integrated plan expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the integrated organization determination must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare and Medicaid coverage criteria, before the applicable integrated plan issues the integrated organization determination decision. The physician or health care professional reviewing the request need not, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

(4) *Integrated reconsideration determinations.* Individuals making an integrated reconsideration determination must be individuals who—

(i) Were neither involved in any previous level of review or decision-making nor a subordinate of any such individual; and

(ii) If deciding an appeal of a denial that is based on lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), are a physician or other appropriate health care professional who have the appropriate clinical expertise in treating the enrollee's condition or disease, and knowledge of Medicare and Medicaid coverage criteria, before the applicable integrated plan issues the integrated reconsideration determination.

(1) *Parties.* (1) The following individuals or entities can request an integrated grievance, integrated organization determination, and integrated reconsideration, and are parties to the case:

(i) The enrollee.

(ii) The enrollee's representative, including any person authorized under State law.

(2) When the term “enrollee” is used throughout §§ 422.629 through 422.634, it includes providers that file a request and authorized representatives consistent with this paragraph, unless otherwise specified.

(3) A provider who is providing treatment to the enrollee may, upon providing notice to the enrollee, request a standard or expedited pre-service integrated reconsideration on behalf of an enrollee.

(4) The following individuals or entities may request an integrated reconsideration and are parties to the case:

(i) An assignee of the enrollee (that is, a physician or other provider who has furnished or intends to furnish a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service).

(ii) Any other provider or entity (other than the applicable integrated plan) who has an appealable interest in the proceeding.

[84 FR 15835, Apr. 16, 2019, as amended at 84 FR 23883, May 23, 2019; 86 FR 6102, Jan. 19, 2021; 87 FR 27897, May 9, 2022; 88 FR 22335, Apr. 12, 2023]

§ 422.630 Integrated grievances.

(a) *General rule.* In lieu of complying with § 422.564, and the grievance requirements of §§ 438.402, 438.406, 438.408, 438.414, and 438.416 of this chapter, each

applicable integrated plan must comply with this section. Each applicable integrated plan must provide meaningful procedures for timely hearing and resolving integrated grievances between enrollees and the applicable integrated plan or any other entity or individual through which the applicable integrated plan provides covered items and services.

(b) *Timing.* An enrollee may file an integrated grievance at any time with the applicable integrated plan.

(c) *Filing.* An enrollee may file an integrated grievance orally or in writing with the applicable integrated plan, or with the State for an integrated grievance related to a Medicaid benefit, if the State has a process for accepting Medicaid grievances.

(d) *Expedited grievances.* An applicable integrated plan must respond to an enrollee's grievance within 24 hours if the complaint involves the applicable integrated plan's—

(1) Decision to invoke an extension relating to an integrated organization determination or integrated reconsideration; or

(2) Refusal to grant an enrollee's request for an expedited integrated organization determination under § 422.631 or expedited integrated reconsideration under § 422.633.

(e) *Resolution and notice.* (1) The applicable integrated plan must resolve standard integrated grievances as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 calendar days from the date it receives the integrated grievance.

(i) All integrated grievances submitted in writing must be responded to in writing.

(ii) Integrated grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) All integrated grievances related to quality of care, regardless of how the integrated grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO with regard to Medicare covered services. For any complaint submitted to a QIO, the applicable integrated plan must cooper-

ate with the QIO in resolving the complaint.

(2) The timeframe for resolving the integrated grievance may be extended by 14 calendar days if the enrollee requests an extension or if the applicable integrated plan justifies the need for additional information and documents how the delay is in the interest of the enrollee. When the applicable integrated plan extends the timeframe, it must—

(i) Make reasonable efforts to promptly notify the enrollee orally of the reasons for the delay; and

(ii) Send written notice to the enrollee of the reasons for the delay immediately, but no later than within 2 calendar days of making the decision to extend the timeframe to resolve the integrated grievance. This notice must explain the right to file an integrated grievance if the enrollee disagrees with the decision to delay.

§ 422.631 Integrated organization determinations.

(a) *General rule.* An applicable integrated plan must adopt and implement a process for enrollees to request that the plan make an integrated organization determination. The process for requesting that the applicable integrated plan make an integrated organization determination must be the same for all covered benefits. Timeframes and notice requirements for integrated organization determinations for Part B drugs are governed by the provisions for Part B drugs in §§ 422.568(b)(2), 422.570(d)(2), and 422.572(a)(2).

(b) *Requests.* The enrollee, or a provider on behalf of an enrollee, may request an integrated organization determination orally or in writing, except for requests for payment, which must be in writing (unless the applicable integrated plan or entity responsible for making the determination has implemented a voluntary policy of accepting verbal payment requests).

(c) *Expedited integrated organization determinations.* (1) An enrollee, or a provider on behalf of an enrollee, may request an expedited integrated organization determination.

(2) The request can be oral or in writing.

(3) The applicable integrated plan must complete an expedited integrated organization determination when the applicable integrated plan determines (based on a request from the enrollee or on its own) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function.

(d) *Timeframes and notice*—(1) *Integrated organization determination notice.*

(i) The applicable integrated plan must send an enrollee a written notice of any adverse decision on an integrated organization determination (including a determination to authorize a service or item in an amount, duration, or scope that is less than the amount previously requested or authorized for an ongoing course of treatment) within the timeframes set forth in this section.

(ii) For an integrated organization determination not reached within the timeframes specified in this section (which constitutes a denial and is thus an adverse decision), the applicable integrated plan must send a notice on the date that the timeframes expire. Such notice must describe all applicable Medicare and Medicaid appeal rights.

(iii) Integrated organization determination notices must be written in plain language, be available in a language and format that is accessible to the enrollee, and explain the following:

(A) The applicable integrated plan's determination.

(B) The date the determination was made.

(C) The date the determination will take effect.

(D) The reasons for the determination.

(E) The enrollee's right to file an integrated reconsideration and the ability for someone else to file an appeal on the enrollee's behalf.

(F) Procedures for exercising enrollee's rights to an integrated reconsideration.

(G) Circumstances under which expedited resolution is available and how to request it.

(H) If applicable, the enrollee's rights to have benefits continue pending the resolution of the integrated appeal process.

(2) *Timing of notice*—(i) *Standard integrated organization determinations.* (A) The applicable integrated plan must send a notice of its integrated organization determination at least 10 days before the date of action (that is, before the date on which a termination, suspension, or reduction becomes effective), in cases where a previously approved service is being reduced, suspended, or terminated, except in circumstances where an exception is permitted under §§ 431.213 and 431.214 of this chapter.

(B) Except as described in paragraph (d)(2)(i)(A) of this section, the applicable integrated plan must send a notice of its integrated organization determination as expeditiously as the enrollee's health condition requires but no later than either of the following:

(1) For a service or item not subject to the prior authorization rules in § 422.122, 14 calendar days after receiving the request for the standard integrated organization determination.

(2) Beginning on or after January 1, 2026, for a service or item subject to the prior authorization rules in § 422.122, 7 calendar days after receiving the request for the standard integrated organization determination.

(ii) *Extensions.* The applicable integrated plan may extend the timeframe for a standard or expedited integrated organization determination by up to 14 calendar days if—

(A) The enrollee or provider requests the extension; or

(B) The applicable integrated plan can show that—

(1) The extension is in the enrollee's interest; and

(2) There is need for additional information and there is a reasonable likelihood that receipt of such information would lead to approval of the request, if received.

(iii) *Notices in cases of extension.* (A) When the applicable integrated plan extends the timeframe, it must notify the enrollee in writing of the reasons

for the delay as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension, and inform the enrollee of the right to file an expedited integrated grievance if he or she disagrees with the applicable integrated plan's decision to grant an extension.

(B) If the applicable integrated plan extends the timeframe for making its integrated organization determination, it must send the notice of its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(iv) *Expedited integrated organization determinations.* (A) The applicable integrated plan must provide notice of its expedited integrated organization determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

(B) If the applicable integrated plan denies the request for an expedited integrated organization determination, it must:

(1) Automatically transfer a request to the standard timeframe and make the determination within the applicable timeframe established in paragraph (d)(2)(i)(B) of this section for a standard integrated organization determination. The timeframe begins the day the applicable integrated plan receives the request for expedited integrated organization determination.

(2) Give the enrollee prompt oral notice of the denial and transfer and subsequently deliver, within 3 calendar days, a written letter that—

(i) Explains that the applicable integrated plan will process the request using the timeframe for standard integrated organization determinations;

(ii) Informs the enrollee of the right to file an expedited integrated grievance if he or she disagrees with the applicable integrated plan's decision not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited integrated organization determination with any physician's support; and

(iv) Provides instructions about the integrated grievance process and its timeframes.

(C) If the applicable integrated plan must receive medical information from noncontract providers, the applicable integrated plan must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited integrated organization determination. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the applicable integrated plan in meeting the required timeframe. Regardless of whether the applicable integrated plan must request information from noncontract providers, the applicable integrated plan is responsible for meeting the timeframe and notice requirements of this section.

(3) *Timeframe for requests for payment.* The applicable integrated plan must process requests for payment according to the "prompt payment" provisions set forth in § 422.520.

(e) *Dismissing a request.* The applicable integrated plan dismisses a standard or expedited integrated organization determination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The individual or entity making the request is not permitted to request an integrated organization determination under § 422.629(l).

(2) The applicable integrated plan determines the party failed to make out a valid request for an integrated organization determination that substantially complies with paragraph (b) of this section.

(3) An enrollee or the enrollee's representative files a request for an integrated organization determination, but the enrollee dies while the request is pending, and both of the following apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the integrated organization determination.

(4) A party filing the integrated organization determination request submits a timely request for withdrawal of

their request for an integrated organization determination with the applicable integrated plan.

(f) *Notice of dismissal.* The applicable integrated plan must mail or otherwise transmit a written notice of the dismissal of the integrated organization determination request to the parties. The notice must state all of the following:

- (1) The reason for the dismissal.
- (2) The right to request that the applicable integrated plan vacate the dismissal action.
- (3) The right to request reconsideration of the dismissal.

(g) *Vacating a dismissal.* If good cause is established, the applicable integrated plan may vacate its dismissal of a request for an integrated organization determination within 6 months from the date of the notice of dismissal.

(h) *Effect of dismissal.* The dismissal of a request for an integrated organization determination is binding unless it is modified or reversed by the applicable integrated plan or vacated under paragraph (g) of this section.

(i) *Withdrawing a request.* A party that requests an integrated organization determination may withdraw its request at any time before the decision is issued by filing a request with the applicable integrated plan.

[84 FR 15835, Apr. 16, 2019, as amended at 84 FR 23883, May 23, 2019; 86 FR 6102, Jan. 19, 2021; 87 FR 27897, May 9, 2022; 89 FR 8977, Feb. 8, 2024]

§ 422.632 Continuation of benefits while the applicable integrated plan reconsideration is pending.

(a) *Definition.* As used in this section, timely files means files for continuation of benefits on or before the later of the following:

- (1) Within 10 calendar days of the applicable integrated plan sending the notice of adverse integrated organization determination.
- (2) The intended effective date of the applicable integrated plan's proposed adverse integrated organization determination.

(b) *Continuation of benefits.* The applicable integrated plan must continue the enrollee's benefits under Parts A

and B of title XVIII and title XIX if all of the following occur:

- (1) The enrollee files the request for an integrated appeal timely in accordance with § 422.633(d);
- (2) The integrated appeal involves the termination, suspension, or reduction of previously authorized services;
- (3) The services were ordered by an authorized provider;
- (4) The period covered by the original authorization has not expired; and
- (5) The enrollee timely files for continuation of benefits.

(c) *Duration of continued or reinstated benefits.* If, at the enrollee's request, the applicable integrated plan continues or reinstates the enrollee's benefits, as described in paragraph (b) of this section, while the integrated reconsideration is pending, the benefits must be continued until—

- (1) The enrollee withdraws the request for an integrated reconsideration;
- (2) The applicable integrated plan issues an integrated reconsideration that is unfavorable to the enrollee related to the benefit that has been continued;
- (3) For an appeal involving Medicaid benefits—

(i) The enrollee fails to file a request for a State fair hearing and continuation of benefits, within 10 calendar days after the applicable integrated plan sends the notice of the integrated reconsideration;

(ii) The enrollee withdraws the appeal or request for a State fair hearing; or

(iii) A State fair hearing office issues a hearing decision adverse to the enrollee.

(d) *Recovery of costs.* In the event the appeal or State fair hearing is adverse to the enrollee—

(1) The applicable integrated plan or State agency may not pursue recovery for costs of services furnished by the applicable integrated plan pending the integrated reconsideration, to the extent that the services were furnished solely under of the requirements of this section.

(2) If, after the integrated reconsideration decision is final, an enrollee requests that Medicaid services continue through a State fair hearing, state

rules on recovery of costs, in accordance with the requirements of § 438.420(d) of this chapter, apply for costs incurred for services furnished pending appeal subsequent to the date of the integrated reconsideration decision.

[84 FR 15835, Apr. 16, 2019, as amended at 86 FR 6103, Jan. 19, 2021]

§ 422.633 Integrated reconsiderations.

(a) *General rule.* An applicable integrated plan may only have one level of integrated reconsideration for an enrollee.

(b) *External medical reviews.* If a State has established an external medical review process, the requirements of § 438.402(c)(1)(i)(B) of this chapter apply to each applicable integrated plan that is a Medicaid managed care organization, as defined in section 1903 of the Act.

(c) *Case file.* Upon request of the enrollee or his or her representative, the applicable integrated plan must provide the enrollee and his or her representative the enrollee's case file, including medical records, other documents and records, and any new or additional evidence considered, relied upon, or generated by the applicable integrated plan (or at the direction of the applicable integrated plan) in connection with the appeal of the integrated organization determination. This information must be provided free of charge and sufficiently in advance of the resolution timeframe for the integrated reconsideration, or subsequent appeal, as specified in this section.

(d) *Timing.* (1) *Timeframe for filing*—An enrollee has 60 calendar days after receipt of the adverse organization determination notice to file a request for an integrated reconsideration with the applicable integrated plan.

(i) The date of receipt of the adverse organization determination is presumed to be 5 calendar days after the date of the integrated organization determination notice, unless there is evidence to the contrary.

(ii) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the applicable integrated plan.

(2) *Oral inquires*—Oral inquires seeking to appeal an adverse integrated organization determination must be treated as a request for an integrated reconsideration (to establish the earliest possible filing date for the appeal).

(3) *Extending the time for filing a request*—(i) *General rule.* If a party or physician acting on behalf of an enrollee shows good cause, the applicable integrated plan may extend the timeframe for filing a request for an integrated reconsideration.

(ii) *How to request an extension of timeframe.* If the 60-day period in which to file a request for an integrated reconsideration has expired, a party to the integrated organization determination or a physician acting on behalf of an enrollee may file a request for integrated reconsideration with the applicable integrated plan. The request for integrated reconsideration and to extend the timeframe must—

(A) Be in writing; and

(B) State why the request for integrated reconsideration was not filed on time.

(e) *Expedited integrated reconsiderations.* (1) Applicable integrated plans must accept requests to expedite integrated reconsiderations from either of the following:

(i) An enrollee.

(ii) A provider making the request on behalf of an enrollee, when the request is not a request for expedited payment.

(2) The request can be oral or in writing.

(3) The applicable integrated plan must grant the request to expedite the integrated reconsideration when it determines (for a request from the enrollee), or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request), that taking the time for a standard resolution could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function.

(4) If an applicable integrated plan denies an enrollee's request for an expedited integrated reconsideration, it must automatically transfer a request to the standard timeframe and make the determination within the 30-day

timeframe established in paragraph (f)(1) of this section for a standard integrated reconsideration. The 30-day period begins with the day the applicable integrated plan receives the request for expedited integrated reconsideration. The applicable integrated plan must give the enrollee prompt oral notice of the decision, and give the enrollee written notice within 2 calendar days. The written notice must do all of the following:

- (i) Include the reason for the denial.
- (ii) Inform the enrollee of the right to file a grievance if the enrollee disagrees with the decision not to expedite, including timeframes and procedures for filing a grievance.
- (iii) Inform the enrollee of the right to resubmit a request for an expedited determination with any physician's support.

(5) If the applicable integrated plan must receive medical information from noncontract providers, the applicable integrated plan must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited integrated reconsideration. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the applicable integrated plan in meeting the required timeframe. Regardless of whether the applicable integrated plan must request information from noncontract providers, the applicable integrated plan is responsible for meeting the timeframe and notice requirements of this section.

(f) *Resolution and notification.* The applicable integrated plan must make integrated reconsidered determinations as expeditiously as the enrollee's health condition requires but no later than the timeframes established in this section. Integrated reconsidered determinations regarding Part B drugs must comply with the timelines governing Part B drugs established in §§ 422.584(d)(1) and 422.590(c) and (e)(2).

(1) *Standard integrated reconsiderations.* The applicable integrated plan must resolve integrated reconsiderations as expeditiously as the enrollee's health condition requires but no later than 30 calendar days from the date of receipt of the request for the in-

tegrated reconsideration. This timeframe may be extended as described in paragraph (f)(3) of this section.

(2) *Expedited integrated reconsiderations.* The applicable integrated plan must resolve expedited integrated reconsiderations as expeditiously as the enrollee's health condition requires but no later than within 72 hours of receipt of the integrated reconsideration. This timeframe may be extended as described in paragraph (f)(3) of this section. In addition to the written notice required under paragraph (f)(4) of this section, the applicable integrated plan must make reasonable efforts to provide prompt oral notice of the expedited resolution to the enrollee.

(3) *Extensions.* (i) The applicable integrated plan may extend the timeframe for resolving any integrated reconsideration other than those concerning Part B drugs by 14 calendar days if—

(A) The enrollee requests the extension; or

(B) The applicable integrated plan can show that—

(1) The extension is in the enrollee's interest; and

(2) There is need for additional information and there is a reasonable likelihood that receipt of such information would lead to approval of the request, if received.

(ii) If the applicable integrated plan extends the timeframe for resolving the integrated reconsideration, it must make reasonable efforts to give the enrollee prompt oral notice of the delay, and give the enrollee written notice within 2 calendar days of making the decision to extend the timeframe to resolve the integrated reconsideration. The notice must include the reason for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the decision to grant an extension.

(4) *Notice of resolution.* The applicable integrated plan must send a written notice to enrollees that includes the integrated reconsidered determination, within the resolution timeframes set forth in this section. The notice of determination must be written in plain language and available in a language and format that is accessible to the enrollee and must explain the following:

(i) The resolution of and basis for the integrated reconsideration and the date it was completed.

(ii) For integrated reconsiderations not resolved wholly in favor of the enrollee:

(A) An explanation of the next level of appeal available under the Medicare and Medicaid programs, and what steps the enrollee must take to pursue the next level of appeal under each program, and how the enrollee can obtain assistance in pursuing the next level of appeal under each program; and

(B) The right to request and receive Medicaid-covered benefits while the next level of appeal is pending, if applicable.

(g) *Withdrawing a request.* The party or physician acting on behalf of an enrollee who files a request for integrated reconsideration may withdraw it by filing a request for withdrawal with the applicable integrated plan.

(h) *Dismissing a request.* The applicable integrated plan dismisses an expedited or standard integrated reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The person or entity requesting an integrated reconsideration is not a proper party to request an integrated reconsideration under § 422.629(l).

(2) The applicable integrated plan determines the party failed to make a valid request for an integrated reconsideration that substantially complies with § 422.629(l) of this section.

(3) The party fails to file the integrated reconsideration request within the proper filing timeframe in accordance with paragraph (d) of this section.

(4) The enrollee or the enrollee's representative files a request for an integrated reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the integrated reconsideration.

(5) A party filing the reconsideration request submits a timely request for withdrawal of their request for an inte-

grated reconsideration with the applicable integrated plan.

(i) *Notice of dismissal.* The applicable integrated plan must mail or otherwise transmit a written notice of the dismissal of the integrated reconsideration request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the applicable integrated plan vacate the dismissal action.

(3) The right to request review of the dismissal by the independent entity.

(j) *Vacating a dismissal.* If good cause is established, the applicable integrated plan may vacate its dismissal of a request for integrated reconsideration within 6 months from the date of the notice of dismissal.

(k) *Effect of dismissal.* The applicable integrated plan's dismissal is binding unless the enrollee or other party requests review by the independent entity in accordance with § 422.590(h) or the dismissal is vacated under paragraph (j) of this section.

[84 FR 15835, Apr. 16, 2019, as amended at 84 FR 23883, May 23, 2019; 84 FR 26579, June 7, 2019; 86 FR 6103, Jan. 19, 2021; 87 FR 27897, May 9, 2022; 89 FR 30827, Apr. 23, 2024]

§ 422.634 Effect.

(a) *Failure of the applicable integrated plan to send timely notice of a determination.* If the applicable integrated plan fails to adhere to the notice and timing for an integrated organization determination or integrated reconsideration, this failure constitutes an adverse determination for the enrollee.

(1) For an integrated organization determination, this means that the enrollee may request an integrated reconsideration.

(2) For integrated reconsiderations of Medicare benefits, this means the applicable integrated plan must forward the case to the independent review entity, in accordance with the timeframes under paragraph (b) of this section and § 422.592. For integrated reconsiderations of Medicaid benefits, this means that an enrollee or other party may file for a State fair hearing in accordance with § 438.408(f) of this chapter, or if applicable, a State external medical review in accordance with § 438.402(c) of this chapter.

(b) *Adverse integrated reconsiderations.*

(1) Subject to paragraph (b)(2) of this section, when the applicable integrated plan affirms, in whole or in part, its adverse integrated organization determination involving a Medicare benefit—

(i) The issues that remain in dispute must be reviewed and resolved by an independent, outside entity that contracts with CMS, in accordance with §§ 422.592 and 422.594 through 422.619;

(ii) For standard integrated reconsiderations, the applicable integrated plan must prepare a written explanation and send the case file to the independent review entity contracted by CMS, as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request (or no later than the expiration of an extension described in § 422.633(f)(3)). The applicable integrated plan must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity; and

(iii) For expedited integrated reconsiderations, the applicable integrated plan must prepare a written explanation and send the case file to the independent review entity contracted by CMS as expeditiously as the enrollee's health condition requires, but no later than within 24 hours of its affirmation (or no later than the expiration of an extension described in § 422.633(f)(3)). The applicable integrated plan must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(2) When the applicable integrated plan affirms, in whole or in part, its adverse integrated organization determination involving a Medicaid benefit, the enrollee or other party (that is not the applicable integrated plan) may initiate a State fair hearing in the timeframe specified in § 438.408(f)(2) following the integrated plan's notice of resolution. If a provider is filing for a State fair hearing on behalf of the enrollee as permitted by State law, the provider needs the written consent of the enrollee, if he or she has not already obtained such consent.

(c) *Final determination.* The reconsidered determination of the applicable

integrated plan is binding on all parties unless it is appealed to the next applicable level. In the event that the enrollee pursues the appeal in multiple forums and receives conflicting decisions, the applicable integrated plan is bound by, and must act in accordance with, decisions favorable to the enrollee.

(d) *Services not furnished while the appeal is pending.* (1) If an applicable integrated plan reverses its decision to deny, limit, or delay services that were not furnished while the appeal was pending, the applicable integrated plan must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than the earlier of—

(i) 72 hours from the date it reverses its decision; or

(ii)(A) With the exception of a Part B drug, 30 calendar days after the date the applicable integrated plan receives the request for the integrated reconsideration (or no later than upon expiration of an extension described in § 422.633(f)); or

(B) For a Part B drug, 7 calendar days after the date the applicable integrated plan receives the request for the integrated reconsideration.

(2) For a Medicaid benefit, if a State fair hearing officer reverses an applicable integrated plan's integrated reconsideration decision to deny, limit, or delay services that were not furnished while the appeal was pending, the applicable integrated plan must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination.

(3) Reversals by the Part C independent review entity, an administrative law judge or attorney adjudicator at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council must be effectuated under same timelines applicable to other MA plans as specified in §§ 422.618 and 422.619.

(e) *Services furnished while the appeal is pending.* If the applicable integrated plan or the State fair hearing officer reverses a decision to deny, limit, or delay Medicaid-covered benefits, and