limited to, the quality of care or services provided, and aspects of interpersonal relationships such as rudeness of a provider or employee, or failure to respect the enrollee's rights regardless of whether remedial action is requested. Grievance includes an enrollee's right to dispute an extension of time proposed by the MCO, PIHP or PAHP to make an authorization decision.

Grievance and appeal system means the processes the MCO, PIHP, or PAHP implements to handle appeals of an adverse benefit determination and grievances, as well as the processes to collect and track information about them.

State fair hearing means the process set forth in subpart E of part 431 of this chapter.

(c) *Applicability.* (1) Subject to paragraph (c)(2) of this section, this subpart applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2017. Until that applicability date, States, MCOs, PIHPs, and PAHPs are required to continue to comply with subpart F contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

(2) Provisions in this part affecting applicable integrated plans, as defined in §422.561 of this chapter, are applicable no later than January 1, 2021.

[81 FR 27853, May 6, 2016, as amended at 84 FR 15844, Apr. 16, 2019; 85 FR 72842, Nov. 13, 2020]

§438.402 General requirements.

(a) *The grievance and appeal system.* Each MCO, PIHP, and PAHP must have a grievance and appeal system in place for enrollees. Non-emergency medical transportation PAHPs, as defined in §438.9, are not subject to this subpart F. For grievances and appeals at the plan level, an applicable integrated plan as defined in §422.561 of this chapter is not subject to this subpart F, and is instead subject to the requirements of §§422.629 through 422.634 of this chapter. For appeals of integrated reconsiderations, applicable integrated plans are subject to §438.408(f).

(b) *Level of appeals.* Each MCO, PIHP, and PAHP may have only one level of appeal for enrollees.

(c) *Filing requirements*—(1) *Authority to file.* (i) An enrollee may file a grievance and request an appeal with the MCO, PIHP, or PAHP. An enrollee may request a State fair hearing after receiving notice under §438.408 that the adverse benefit determination is upheld.

(A) *Deemed exhaustion of appeals processes.* In the case of an MCO, PIHP, or PAHP that fails to adhere to the notice and timing requirements in §438.408, the enrollee is deemed to have exhausted the MCO's, PIHP's, or PAHP's appeals process. The enrollee may initiate a State fair hearing.

(B) *External medical review.* The State may offer and arrange for an external medical review if the following conditions are met.

(*1*) The review must be at the enrollee's option and must not be required before or used as a deterrent to proceeding to the State fair hearing.

(*2*) The review must be independent of both the State and MCO, PIHP, or PAHP.

(*3*) The review must be offered without any cost to the enrollee.

(*4*) The review must not extend any of the timeframes specified in §438.408 and must not disrupt the continuation of benefits in §438.420.

(ii) If State law permits and with the written consent of the enrollee, a provider or an authorized representative may request an appeal or file a grievance, or request a State fair hearing, on behalf of an enrollee. When the term ''enrollee'' is used throughout subpart F of this part, it includes providers and authorized representatives consistent with this paragraph, with the exception that providers cannot request continuation of benefits as specified in §438.420(b)(5).

(2) *Timing*—(i) *Grievance.* An enrollee may file a grievance with the MCO, PIHP, or PAHP at any time.

(ii) *Appeal.* Following receipt of a notification of an adverse benefit determination by an MCO, PIHP, or PAHP, an enrollee has 60 calendar days from the date on the adverse benefit determination notice in which to file a request for an appeal to the managed care plan.

(3) *Procedures*—(i) *Grievance.* The enrollee may file a grievance either orally or in writing and, as determined by

the State, either with the State or with the MCO, PIHP, or PAHP.

(ii) *Appeal.* The enrollee may request an appeal either orally or in writing.

[81 FR 27853, May 6, 2016, as amended at 84 FR 15844, Apr. 16, 2019; 85 FR 72842, Nov. 13, 2020]

§ 438.404 Timely and adequate notice of adverse benefit determination.

(a) *Notice.* The MCO, PIHP, or PAHP must give enrollees timely and adequate notice of an adverse benefit determination in writing consistent with the requirements below and in § 438.10.

(b) *Content of notice.* The notice must explain the following:

(1) The adverse benefit determination the MCO, PIHP, or PAHP has made or intends to make.

(2) The reasons for the adverse benefit determination, including the right of the enrollee to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the enrollee's adverse benefit determination. Such information includes medical necessity criteria, and any processes, strategies, or evidentiary standards used in setting coverage limits.

(3) The enrollee's right to request an appeal of the MCO's, PIHP's, or PAHP's adverse benefit determination, including information on exhausting the MCO's, PIHP's, or PAHP's one level of appeal described at § 438.402(b) and the right to request a State fair hearing consistent with § 438.402(c).

(4) The procedures for exercising the rights specified in this paragraph (b).

(5) The circumstances under which an appeal process can be expedited and how to request it.

(6) The enrollee's right to have benefits continue pending resolution of the appeal, how to request that benefits be continued, and the circumstances, consistent with state policy, under which the enrollee may be required to pay the costs of these services.

(c) *Timing of notice.* The MCO, PIHP, or PAHP must mail the notice within the following timeframes:

(1) For termination, suspension, or reduction of previously authorized Medicaid-covered services, within the timeframes specified in §§ 431.211, 431.213, and 431.214 of this chapter.

(2) For denial of payment, at the time of any action affecting the claim.

(3) For standard service authorization decisions that deny or limit services, within the timeframe specified in § 438.210(d)(1).

(4) If the MCO, PIHP, or PAHP meets the criteria set forth for extending the timeframe for standard service authorization decisions consistent with § 438.210(d)(1)(ii), it must—

(i) Give the enrollee written notice of the reason for the decision to extend the timeframe and inform the enrollee of the right to file a grievance if he or she disagrees with that decision; and

(ii) Issue and carry out its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(5) For service authorization decisions not reached within the timeframes specified in § 438.210(d) (which constitutes a denial and is thus an adverse benefit determination), on the date that the timeframes expire.

(6) For expedited service authorization decisions, within the timeframes specified in § 438.210(d)(2).

§ 438.406 Handling of grievances and appeals.

(a) *General requirements.* In handling grievances and appeals, each MCO, PIHP, and PAHP must give enrollees any reasonable assistance in completing forms and taking other procedural steps related to a grievance or appeal. This includes, but is not limited to, auxiliary aids and services upon request, such as providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability.

(b) *Special requirements.* An MCO's, PIHP's or PAHP's process for handling enrollee grievances and appeals of adverse benefit determinations must:

(1) Acknowledge receipt of each grievance and appeal.

(2) Ensure that the individuals who make decisions on grievances and appeals are individuals—

(i) Who were neither involved in any previous level of review or decision-making nor a subordinate of any such individual.