

E. Grievance System (Subpart F)

Proposed subpart F is based on section 1902(a)(3) of the Act, (which requires a State plan to provide an opportunity for a fair hearing to any person whose request for assistance is denied or not acted upon promptly), section 1902(a)(4) of the Act, (which authorizes the Secretary to specify methods of administration that are “necessary” for “proper and efficient administration”), and section 1932(b)(4) of the Act, (which requires that MCOs have an internal grievance procedure under which a Medicaid enrollee, or a provider on behalf of an enrollee, may challenge the denial of coverage of, or payment by, the MCO).

In this subpart, we proposed regulations that lay out the elements of the grievance system required under section 1932(b)(4) of the Act, and how it interfaces with the State fair hearing requirements in section 1902(a)(3). We defined terms, described what constitutes a notice of action, and addressed how grievances and appeals must be handled, including timeframes for taking action. We included a process for expedited resolution of appeals in specific circumstances; addressed the requirement for continuation of benefits; and laid out the requirements relating to record keeping, monitoring and effectuation of reversed appeal resolutions.

We proposed conforming amendments to part 431 to reflect changes in terminology and other new provisions enacted in the BBA. We also made conforming changes to the fair hearing regulations in subpart E of part 431, to reflect the MCO grievance and appeals process in subpart F of part 438. We note that we revised §431.244(f)(3) to require State approval for direct access to an expedited State fair

hearing for MCO and PIHP enrollees. Due to the close relationship of the subject matter with subpart F, comments and responses regarding part 431 are addressed in this subpart.

1. Statutory Basis and Definitions (Proposed §438.400)

Definitions of terms used in proposed subpart F are found in proposed §438.400 and have the following meanings:

Action means, in the case of an MCO or PIHP or any of its providers,

- The denial or limited authorization of a requested service, including the type or level of service;

- The reduction, suspension, or termination of a previously authorized service;

- The denial, in whole or in part, of payment for a service; or

- For a resident of a rural area with only one MCO or PIHP, the denial of a Medicaid enrollee's request to exercise his or her right to obtain services outside the network.

Appeal means a request for review of an action, as "action" is defined in this subpart.

Grievance is defined as an expression of dissatisfaction about any matter other than an action. This term can also be used to refer to the overall system that includes grievances and appeals handled at the MCO or PIHP level and access to the State fair hearing Process. Possible subjects for grievances include, but are not limited to, the quality of care or services provided, aspects of interpersonal relationships such as rudeness of a provider or employee, or failure to respect the enrollee's rights.

Proposed §438.400 contained the definition of a “governing body.” We, however, had not proposed regulatory requirements for a governing body. Therefore, we are removing the definition of a governing body in the final rule.

We received the following comments on these definitions.

Comment: One commenter felt that having several potentially conflicting Federal statutes and State laws related to a health care plan’s grievance system is troubling for the plans. They asked that, if a Patients’ Bill of Rights is enacted, CMS review the provisions of this regulation to make it consistent with the mandate under that legislation, as well as ERISA rules.

Response: We agree with the commenter. If a Patients’ Bill of Rights is enacted, we of course would be required to conform to the new statute if it applied to Medicaid, but even if it did not, we would review the provisions and consider making changes if it is appropriate for the Medicaid program.

Comment: Many commenters believe that the definition of “action” must include the failure to furnish services in a timely manner, the failure to resolve an appeal in a timely manner, or the denial of an enrollee’s request to disenroll. They argued that if a plan delays furnishing services or adjudicating a claim in a timely manner, no “action” is triggered. Therefore, the enrollee would be denied his or her right under section 1902(a)(3) to a fair hearing if a claim medical assistance is “not acted upon with reasonable promptness.”

Response: We agree that section 1902(a)(3) of the Act requires access to a State fair hearing for those requests not acted upon in a timely manner, and therefore, in

§438.400(b) we have modified the definition of “action” to include unreasonable delays in services, or appeals not acted upon within the timeframes provided in §438.408(b). However, we disagree that a denial of a request to disenroll constitutes an "action," as it addresses an issue separate from those specific denials, limitations, reductions, or suspensions of services that trigger fair hearing requirements.

Comment: Some commenters believe that the grievance and appeals provisions should apply to PAHPs as well as to MCOs and PIHPs.

Response: We agree that PAHP enrollees should have the right to appeal denials, but believe that direct access to the existing fee-for-service fair hearing process is the more appropriate vehicle for this in the case of PAHPs. Therefore, in response to this comment, we have revised the fair hearing regulations in subpart E of part 431 to expressly reference PAHP enrollees as having a right to a fair hearing under those provisions in the case of an "action." In general, we believe that the State should decide how best to address grievances involving PAHPs that do not involve an action, since they are often individual physicians or small group practices and cannot be expected to have the administrative structure to support a grievance process.

Comment: Several commenters disagreed that the independent professional judgment of providers should automatically trigger an action in the same manner as a denial from an MCO or PIHP. They believed that it is sometimes impossible for the MCO or PIHP to know when a provider has denied a service, or offered an alternative form of treatment that may or may not be a denial. They requested that providers be removed from the “action” definition.

Response: We agree with the commenters. Since a provider is making independent professional judgments as to the care and treatment of enrollees, his or her denial of a particular request, or the suggestion of an alternative should not automatically trigger a formal notice of appeal rights from the MCO or PIHP. We have removed “or any of its providers” from the definition of an “action.” However, anytime an enrollee challenges the decision of a provider to the MCO or PIHP, an action is triggered if the MCO or PIHP affirms the provider’s decision, triggering a notice from the MCO or PIHP.

Comment: Many commenters wanted the regulations to provide expressly for a “quality of care” grievance in cases in which the enrollee believed that any aspect of his or her care was substandard, or could have caused them harm. These commenters recommended that the State be required to review any such "quality" grievance that was not disposed of to the enrollee’s satisfaction. Some commenters wanted these grievances to be reviewable by a State fair hearing.

Response: We believe that those enrollee complaints not meeting the standard of an appeal should be treated uniformly under Federal statute. The definition of “grievance” includes “quality of care” and it should be up to the State to decide whether or not a review, or a mechanism allowing State review, is necessary. We also believe that an enrollee only has the right to a State fair hearing under section 1902(a)(3) in cases that involve an “action,” since section 1902(a)(3) refers to a denial of medical assistance, or a case in which a claim for assistance is "not acted upon," and not a case in which

there are concerns about the quality of the assistance. We believe that the quality assurance requirements in subpart D of part 438 address the commenter's concerns.

Comment: One commenter felt that appeal rights should be extended to providers in managed care systems. They argued that this is notable considering the appeal rights extended to MCOs in the right to pre-termination hearings.

Response: The grievance and appeal rights in this subpart implement statutory provisions that grant rights to Medicaid beneficiaries, not providers. The right to a fair hearing in section 1902(a)(3) applies to an "individual" whose claim for medical assistance is denied or not acted upon. The statutory requirement in section 1932(b)(4) that MCOs have grievance procedures similarly applies to "an enrollee. . .or a provider on behalf of an enrollee. . ." (Emphasis added.) While it is true that the statute provides for the right to a hearing before an MCO contract is terminated, there is no statutory provision for an appeal right for providers subcontracting with managed care plans. While States are free to provide such rights, and information must be provided about such rights where they exist (see section A. above), there are no such rights under Federal statute. We defer to congressional intent on this issue, and have not provided for any subcontracting provider appeal rights in this final rule.

2. General Requirements (Proposed §438.402)

Proposed §438.402 required each MCO and PIHP to have a grievance system in place for enrollees that includes a grievance process, an appeal process, and access to the State's fair hearing system.

Proposed §438.402(b)(1) specified that an enrollee may file a grievance or an MCO or PIHP level appeal, and may request a State fair hearing. In addition, as provided in section 1932(b)(4), the proposed rule provides that a provider, acting on behalf of an enrollee (with the enrollee's written consent) may file an appeal of a "denial of coverage of or payment for" assistance, or an "action." However, under proposed §438.402(b)(1)(ii), the provider could not file a grievance or request a State fair hearing on behalf of the enrollee.

Under §438.402(b)(2), we proposed timeframes within which the enrollee or provider (on the enrollee's behalf) may file an appeal. Our intent was to mirror the filing timeframes for a State fair hearing, that is, a reasonable amount of time up to 90 days. In addition, we incorporated the longstanding policy at section 2901.3 of the State Medicaid Manual that beneficiaries be given a minimum of 20 days to file an appeal. We believe that this policy gives beneficiaries a reasonable amount of time to file an appeal. Therefore, the proposed regulation required that the State specifies a timeframe for filing an appeal that is no less than 20 days or more than 90 days from the date of the MCO's or PIHP's notice of action. Within this timeframe, the enrollee (or the provider on his or her behalf) may file an appeal, and in a State that does not require exhaustion of the MCO and PIHP level appeals, the enrollee may request a State fair hearing.

In proposed §438.402(b)(3), we specified the manner in which enrollees may file grievances, and enrollees (or a provider on the enrollee's behalf) may file an appeal. For grievances, the enrollee may file either orally or in writing, either with the State or the MCO or PIHP, as determined by the State. The enrollee (or the provider on the

enrollee's behalf) was permitted to file an appeal either orally or in writing, and unless he or she requests expedited resolution, was required to follow an oral filing with a written, signed, appeal. While enrollees were permitted to start the appeal clock with an oral request, under the proposed rule, they were required under the proposed rule to follow it with a written request, as we determined that a written appeal best documents the issue being appealed. In expedited situations, the proposed rule provided that the enrollee was not required to put the appeal in writing.

Comment: A few commenters believed that permitting States to require the exhaustion of internal MCO or PIHP appeals procedures was unwarranted, and favored appeal rights administered by a state agency using the Federal fair hearing regulations. Other commenters believed that since MCOs are responsible for coordinating care and making coverage decisions, enrollees should be required to utilize their internal appeals process first before filing for a State fair hearing.

Response: We disagree with both sets of commenters. With respect to the commenters opposing an internal grievance procedure, section 1932(b)(4) actually requires that such a procedure be available, and that enrollees be permitted to "challenge" a "denial of coverage of, or payment for" services under such procedures. Thus, using exclusively a State administered fair hearing mechanism was not even an option under the law. Furthermore, providing for an MCO/PIHP level of review is consistent with the appeals rules under the Medicare+Choice program, and most versions of Patients Bill of Rights legislation. We believe that as long as the timeframes and notice requirements conform with what is allowed under direct access, an internal system is a proper and

efficient way to adjudicate appeals. However, we also believe that the State should have full discretion when it comes to whether to require the utilization of the required internal appeals process, or permit direct access to State fair hearing.

Comment: Some commenters found that the word “grievance,” referring to the overall system as well as a particular avenue of adjudication, is inherently confusing. They recommended changing “grievance system” to something such as the “dispute resolution process” or “complaint process.” Others felt that the definition was too broad, triggering rights where a different avenue for resolution would make more sense.

Response: While we refer to the overall process as the “grievance system,” States are free to call it by any name they prefer. We chose “grievance system” over terms such as “dispute resolution process” or “complaint process” because this is the term used in section 1932(b)(4), and the other terms suggested by the commenters were too informal. To some people, “complaint” conjures up ideas of more trivial matters, while “dispute resolution” is sometimes associated with arbitration, which connotes a less strict standard than we wanted to convey. While we based our reference to the overall system on the reference to “an internal grievance procedure” in section 1932(b)(4), our use of the term “grievance” to refer to disputes not resulting from an “action” tracks the approach in the Medicare+Choice regulations, and is based on the broad connotations of the word grievance to capture a variety of types of complaints. We believe that the timeframes and other administrative requirements in this final rule provide sufficient State flexibility to not be a burden on the grievance system.

Comment: Many commenters recommended additional general requirements for the grievance system. These recommendations included specific terms in the regulations requiring: (1) that all processes, policies, and procedures meet the conditions set forth in this subpart; (2) a State's written approval of an MCO's or PHP's policies and procedures before implementation; (3) a governing body responsible for effective operation of the system including disposing of grievances and resolving appeals; (4) assurance that punitive action is neither threatened nor taken against a provider who requests or supports a grievance or appeal; (5) acceptance of grievances and appeals from the enrollee or his or her representative; (6) the provision of information required under this subpart, (7) the referral to the State of quality of care grievances in which the enrollee is dissatisfied; and (8) that providers be required to give notice in accordance with §438.404(d).

Response: We believe that many of the above suggested requirements are already addressed in this final rule, either directly or implicitly. For example, we believe that while it would be clear without any explicit statement that grievance processes, policies and procedures must be consistent with the regulatory requirements in part F, §438.228 already expressly requires States to ensure, through its contracts, that MCOs and PIHPs have grievance systems that satisfy the requirements of this subpart. This includes the requirement on States to conduct random reviews of MCOs and PIHPs to ensure that they are notifying enrollees in a timely manner. The acceptance of appeals and grievances from the enrollee or a representative is similarly already provided for, as is the requirement, in §438.10, for provision of information on appeals. We have addressed in section A of this preamble the commenters' suggestion for an assurance of no punitive

action for requesting an appeal. Most of the other suggestions above would in our view most appropriately be addressed by the States without further Federal regulation.

Comment: Many commenters believed that a State should not be permitted to establish a deadline for appealing an adverse action that is less than 30 days, even though shorter periods are now permissible in the fee-for-service Medicaid program.

Response: As stated in the introduction, our intent was to mirror the filing timeframes for the State fair hearing; that is, a reasonable amount of time up to 90 days. In addition, we incorporated the longstanding policy at section 2901.3 of the State Medicaid Manual that beneficiaries be given a minimum of 20 days to file an appeal. We believe that this policy gives beneficiaries a reasonable amount of time to file an appeal, while providing States with the flexibility to tailor those timeframes to their particular internal and State procedures. Therefore, we will retain the requirement that the State specify a timeframe for filing an appeal that is no less than 20 days and does not exceed 90 days from the date of the MCO's or PIHP's notice of action.

Comment: One commenter objected to the fact that the proposed rule would allow providers, with written consent, to file an appeal on behalf of the enrollee, but prohibit providers from acting as an authorized representative for grievances or State fair hearings.

Response: As noted in section E. 1. above, we have limited the right to request a fair hearing, and the right to appeal a denial of coverage, to enrollees, and to providers on behalf of enrollees, in deference to our interpretation of congressional intent. In the case of grievances, since these are likely to involve a provider, we have limited the right to file

a grievance to an enrollee. The commenter, however, correctly notes that we have not just denied a provider the right to file a grievance or fair hearing request on behalf of an enrollee, but have affirmatively prohibited providers from doing so, through the second sentence in proposed §438.402(b)(1)(ii). In considering this comment, we have determined that we do not wish to prohibit providers from acting as authorized representatives for grievances, appeals and state fair hearings, if the State wishes to provide them with this right. Since the current prohibition would pre-empt a State law to the contrary, we are, in response to this comment, changing the second sentence in proposed §438.402(b)(1)(ii) to read, "A provider may file a grievance or fair hearing request on behalf of an enrollee if the State permits the provider to act as the enrollee's authorized representative in doing so."

3. Notice of Action (Proposed §438.404)

Under the proposed rule, the notice MCOs and PIHPs are required to provide to enrollees under proposed §438.404 would be the first step in the grievance system. It would serve as the enrollee's first formal indication that the MCO or PIHP will or has taken action, such as denying payment or denying, limiting, reducing, suspending or terminating a service through a service authorization decision. We proposed in §438.404(a) that the notice meet the language and format requirements of proposed §438.10(c) and (d) of this chapter to ensure ease of understanding. The notice must include the elements that are listed in proposed §438.404(b), as follows:

- The action the MCO or PIHP or its contractor has taken or intends to take.
- The reasons for the action.

- The enrollee's or the provider's right to file an MCO or PIHP appeal.
- If the State does not require the enrollee to exhaust the MCO or PIHP level appeal procedures, the enrollee's right to request a State fair hearing.
- The procedures for exercising the rights specified in this section.
- The circumstances under which expedited resolution of an appeal is available, and how to request it.
- The enrollee's right to have benefits continue pending resolution of the appeal, how to request that benefits be continued, and the circumstances under which the enrollee may be required to pay the costs of these services.

In proposed §438.404(c), we specified the timeframes in which the MCO and PIHP must mail the notices. Under proposed §438.404(c)(1), timeframes for notices for the reduction, suspension, or termination of previously authorized services are governed by the State fair hearing regulations found in 42 CFR 431 subpart E. While some MCOs and PIHPs may find the advance notice requirement inappropriate, there are exceptions to advance notice that allow notice to be given on the date of the action (see §431.213). These exceptions would cover the situation in which a provider believes an immediate change in care is appropriate for the health condition of the enrollee. For denial of payment, we required in proposed §438.404(c)(2) that notice be given at the time of any action affecting the claim. Proposed §438.404(c)(3) and (c)(4) required that for standard service authorization decisions that deny or limit services, notice must be given within the timeframes specified in §438.210(d). Further, if the MCO or PIHP were to extend the timeframe in accordance with proposed §438.210(d), it would have to give the enrollee

written notice of the reason for the decision to extend the timeframe, inform the enrollee of the right to file a grievance if he or she disagrees with that decision, and issue and carry out its determination as expeditiously as the enrollee's health conditions requires and no later than the date the extension expires. In situations in which the service authorization decision is not reached within specified timeframes, and the failure to authorize a decision constitutes an adverse decision, we proposed at §438.404(c)(5) that notice be mailed on the date that the timeframe for authorizing services expires without an authorization decision being made. Finally, for expedited service authorization decisions, under the proposed rule notice had to be given within the timeframes specified in proposed §438.210(e) (recodified in this final rule at §438.210(d)).

Comment: Several commenters believed that a strict application of the proposed notice requirement would be burdensome, especially if applied to decisions of primary care physicians (PCPs) made without involvement of the MCO or PHP. Commenters also asked that CMS distinguish between claims that involve liability where the enrollee is actually billed, versus where there is no actual payment liability. Some commenters contended that MCOs and PIHPs do not always know when their providers deny services, making it difficult for them to comply with the notice requirements. Another commenter was concerned with §438.404(b)(1) requiring a notice to explain the action the MCO or PIHP or its contractor has taken or intends to take. They felt that "contractor" could be read as being a provider. They requested clarification.

Response: We agree with the commenters that a provider, using his or her professional judgement in making a determination of medical necessity, should not

trigger a notice by reason of recommending against or preferring an alternative to a particular treatment. As discussed above, in response to comments received (including this comment), we have removed the word "provider" from the definition of "action" triggering notice obligations and appeal rights. As used in §438.404(b)(1), a "contractor" would not include a provider, but rather any entity in which an MCO or PIHP delegated this particular authority/responsibility. However, an enrollee retains the right to request that the MCO or PIHP provide a particular service against the advice of a provider, triggering the requirement of a notice from that MCO or PIHP if the request results in a denial, reduction, or suspension. We disagree that notice rights are triggered only when a beneficiary is actually held liable for a particular claim. An action that may include a claim arising from a third party (such as, a hospital) because an MCO or PIHP refused to pay the claim. Even though the hospital may choose not to bill the beneficiary, a denial for payment of a service has occurred, triggering a notice to the beneficiary that the claim was denied. This ensures that a beneficiary is made aware of his or her appeal rights in case they are billed by a third party.

Comment: Several commenters noted that they do not believe that the expiration of an approved number of visits should be considered a termination. They noted that the enrollee is free to request that the service be continued, but that this request should be treated as a new request for a service. Other commenters expressed the opposite view; they believe that re-authorization of a service at a lower level than previously received, or a denial of re-authorization, is a termination or reduction of the service and should require notice and the continuation of benefits pending appeal.

Response: We agree with the first set of commenters that the expiration of an approved number of visits does not constitute a termination for purposes of notice and continuation of benefits. Likewise, when a prescription (including refills) runs out and the enrollee requests another prescription, this is a new request not a termination of benefits. In these circumstances, the MCO or PIHP would not need to send a notice or continue benefits pending the outcome of an appeal or State fair hearing. If the enrollee requests a re-authorization that the MCO or PIHP denies, the MCO or PIHP must treat this request as a new request for service authorization and provide notice of the denial or limitation. We disagree with the second commenters that a denial of authorization for additional days is a "termination," since the enrollee had no expectation of coverage on those days, and this was thus simply a denial of a new request, not a termination of services the enrollee had a right to expect to continue.

We believe that the proposed rule already clearly reflected the above interpretation. In the definition of "Action," the reference to a "reduction, suspension, or termination" in the proposed rule was qualified by the phrase, "of a previously authorized service." Thus, the cessation of services because the authorization expired would not be an "action," because services after the date when the authorization expired would not be "previously authorized." In proposed §438.404(c)(1), the reference to timeframes for a notice of a "termination, suspension, or reduction" was similarly qualified by "of previously authorized Medicaid-covered services." In proposed §438.420(b), specifically governing the continuation of services, the right to continued benefits is expressly conditioned on the "[t]he appeal involv[ing] the termination, suspension, or reduction of a

previously authorized course of treatment." Again, we believe it is clear that if additional days were not authorized, ending treatment as provided in the original authorization would not constitute a termination triggering the right to continued benefits. We have made one change in this rule in response to this comment, however. In a case in which services which were "previously authorized" are continued or reinstated at the request of the enrollee pending appeal, and during this continuation period, the period of authorization expires, services may be terminated as provided in the original authorization. We have added a new §438.420(c)(4) to make this clear.

Comment: One commenter believed that CMS underestimated the true burden associated with MCO and PIHP notices, suggesting that it is closer to 20 minutes than 30 seconds per notice.

Response: We address this issue under the Collection of Information Requirements section of this preamble.

Comment: We received many comments regarding the elements of a notice. Several commenters suggested that the written notice requirements of proposed §434.404 be modified to mirror the existing State fair hearing regulations. Other commenters did not believe that there were sufficient protections in place to ensure that enrollees not only have rights, but have effective notice of those rights. These other commenters recommended additional requirements addressing the right to request a State fair hearing, the right to present evidence, how to contact the MCO or PHP for assistance, how to obtain copies of enrollee records, the right of an enrollee to represent himself or herself or use counsel, and the right to be free from any negative impact from having filed an

appeal. Several commenters were concerned that while oral requests for standard appeals must be followed up in writing, there was no requirement that enrollees be told this in the notice. They wanted to see this added.

Response: We agree that information given by MCOs and PIHPs should generally contain the information required by the State fair hearing notices. However, the provision of most of this information is required under the information requirements in §438.10(g)(1) and the content requirements for a notice in §438.404. These requirements will ensure that enrollees are informed, for example, that an oral request for a standard appeal will not be pursued unless it is followed up in writing, of the enrollee's right to a hearing, the method for having a hearing, and circumstances surrounding continuation of benefits, if applicable. We have previously addressed the comment on language concerning negative actions by an MCO or PIHP.

Comment: One commenter noted that §438.404(c)(6) included an incorrect reference. The reference to §438.210(e) should read “§438.210(d).”

Response: We agree with the commenter. We have made the appropriate change in §438.404(c)(6) by correcting the cross reference to read §438.210(d).

4. Handling of Grievances and Appeals (Proposed §438.406)

Section 438.406 proposed to set forth how grievances and appeals must be handled. The general requirement for handling grievances and appeals would require MCOs and PIHPs to do the following:

- Give enrollees any reasonable assistance in completing forms and taking other procedural steps.

- Acknowledge receipt of each grievance and appeal.
- Ensure that individuals who make decisions on grievances and appeals are individuals who were not involved in any previous level of review or decision making and who, if deciding an appeal of a denial that is based on lack of medical necessity, a grievance regarding denial of expedited resolution of an appeal, or a grievance or appeal that involves clinical issues, are health care professionals who have the appropriate clinical expertise in treating the enrollee's condition or disease.

We would require the MCO and PIHP, at proposed §438.406(a)(1), that the “reasonable assistance” provided to enrollees include interpreter services and toll free numbers that have adequate TTY/TTD and interpreter capability. By including these as examples of types of assistance required to meet certain needs, we did not intend that other reasonable assistance need not be given. We believe, for example, that MCOs and PIHPs are required by this provision to provide reasonable assistance to meet other needs of enrollees, and assisting enrollees who have low-literacy abilities.

Proposed §438.406(b) specified the following requirements that the appeals process would have to meet:

- Provide that oral inquiries seeking to appeal an action are treated as appeals and must be confirmed in writing, unless the enrollee or the provider requests expedited resolution. This is required in order to establish the earliest possible filing date for the appeal.
- Provide the enrollee a reasonable opportunity to present evidence, and allegations of fact or law, in person as well as in writing.

- Provide the enroll and his or her representative the opportunity, before and during the appeals process, to examine the enrollee's case file, including medical records, and any other documents and records considered during the appeals process.
- Include, as parties to the appeal, the enrollee and his or her representative or the legal representative of a deceased enrollee's estate.

Comment: One commenter was unclear whether the proposed rule permitted conducting State fair hearings using a video-conferencing system. The commenter noted that many states now use this technology, with videoconference facilities in numerous locations. Multiple sites can be linked to make it more convenient for all parties to participate in the hearing, reducing travel costs, and conserving time.

Response: Nothing in the statute or regulation prevents MCOs, PIHPs, or States from using videoconferencing equipment as long they adhere to the evidentiary rules described in parts 431 and 438.

Comment: Several commenters recommended that CMS establish more general standards regarding the qualifications of hearings officers. Commenters were concerned with the burden of finding providers with clinical expertise for a voluminous number of cases. They requested that it be permissible to either use physicians or other types of providers with appropriate clinical expertise. Other commenters recommended being more specific in linking certain cases to a particular area of expertise. For example, one commenter wanted language ensuring that all grievances and appeals involving care to a child be reviewed by pediatricians and pediatric specialists.

Response: We believe that it is important for adjudicators to have clinical training appropriate for the case in which they are presiding. However, we are leaving the definition of “appropriate clinical expertise” to be defined by the States. This allows States to decide what clinical expertise level is necessary to fit its particular appeals process and volume of cases.

Comment: Several commenters suggested adding “but not limited to” to §438.406(a)(1) where it includes examples of enrollee assistance with grievance and appeals procedures. They believed that this addition would make the language of the regulation comport with the expressed intent of CMS.

Response: We agree with the commenters, and in response to this comment, we have added "but is not limited to" in §438.406(a)(1).

Comment: Several commenters urged CMS to require MCOs and PHPs to have an adequately staffed office designated as the central point for enrollee issues, including grievances and appeals. This would ensure that the processing is someone’s job, and not viewed as a chore that is handled on an ad hoc basis.

Response: We disagree with the commenters. As long as States can ensure that those requirements in §438.406 are met, we believe that it should be their decision as to how best an MCO or PIHP can fulfill those requirements.

Comment: Several commenters questioned the impartiality of an internal appeals system, and felt that CMS should add language to the regulation preventing any employees of the MCO or PHP from being final decision makers on coverage decisions.

Response: In both the Medicare and Medicaid programs, the Congress has provided for an initial level of review of enrollee appeals at the managed care organization level. We believe that the use of the words “internal grievance procedure” in section 1932(b)(4) indicates that the Congress contemplated that review be performed by MCO employees. Within this context, this final rule requires that the decision-makers not be individuals involved in any previous level of review, and either be physicians or have the clinical expertise needed to make a decision involving the enrollee’s particular condition or disease. We believe that these requirements help insure that internal decisions will be as objective as possible. With respect to the “final decision” on a coverage question, all MCO or PIHP coverage decisions are subject to review by non-MCO employees at the State fair hearing level. We believe that those safeguards are reasonable and necessary at the internal appeals level.

Comment: Several commenters believed that we should require MCOs and PHPs to explicitly state that enrollees may obtain copies of their records.

Response: Section 438.406(b)(3) requires that MCOs and PIHPs provide the enrollee and his or her representative with the opportunity to examine the enrollee’s case file, including medical records, and any other documents and records considered during the appeals process. However, we believe that the State is in the best position to decide in what way enrollees must be notified about this right.

5. Resolution and notification: Grievances and appeals. (Proposed §438.408)

In proposed §438.408(a), we required that the MCO or PIHP dispose of each grievance and resolve each appeal, and provide notice, as expeditiously as the enrollee’s

health condition requires. In addition, this section required that the State establish timeframes for disposition of grievances and resolution of appeals, not to exceed the specific timeframes proposed in this section.

While we proposed timeframes to resolve appeals, we realize that the Congress, as part of proposals for a patient's bill of rights, is considering several other timeframes for internal MCO appeals. Some of these proposals would apply the timeframes to the Medicaid program. If these proposals were enacted, such statutory timeframes would supersede those set forth in this final rule.

Under proposed §438.408(b), we established the specific maximum timeframes for disposition of grievances and resolution of appeals. For the standard disposition of a grievance and notice to affected parties, the State may establish a timeframe for disposition that may not exceed 90 days from the day the MCO or PIHP receives the grievance. For standard resolution of an appeal and notice to affected parties, proposed §438.408(b)(2) required that the State establish a timeframe no longer than 45 days from the day the MCO or PIHP receives the appeal. However, this proposed timeframe could be extended under proposed §438.408(c), which specified that the MCO or PIHP may extend the timeframe by up to 14 calendar days if the enrollee requests the extension, or the MCO or PIHP shows (to the satisfaction of the State agency, upon its request) that there is need for additional information and how the delay is in the enrollee's interest.

Proposed §438.408(b)(3) provided a maximum timeframe for expedited resolution of appeals and notice to affected parties. We required that the State establish a timeframe no longer than 3 working days after the MCO or PIHP receives the appeal.

We believe that expedited resolution is necessary to ensure that appeals of situations that potentially place an enrollee's health in jeopardy are not delayed. Although States have historically instituted different processes to protect beneficiaries, we believe that a standardized expedited appeal process is needed to protect beneficiaries in a capitated health care delivery system. Further, this is an important beneficiary protection and is necessary to ensure that the overall timeframe of 90 days for a decision at the State fair hearing (excluding the time the beneficiary takes to file for a State fair hearing) can be met in all cases. However, similar to standard resolution of appeals, we proposed that this expedited timeframe can also be extended by 14 calendar days if the enrollee requests extension or the MCO or PIHP shows (to the satisfaction of the State agency, upon its request) that there is need for additional information and how the delay is in the enrollee's interest.

We proposed certain parameters for the extension process. Under proposed §438.408(c)(2), if the MCO or PIHP grants itself an extension, it is required to notify the enrollee in writing of the reason for the delay. In §438.408(d), we required the State to establish the method MCOs and PIHPs will use to notify an enrollee of the disposition of a grievance. Under proposed §438.408(e), we specified that written notice of the appeal resolution must include the following:

- The results of the resolution process and the date it was completed.
- For appeals not resolved in favor of the enrollee, the enrollee's right to request a

State fair hearing and how to do so, the right to request to receive continuation of

benefits, and that the enrollee may be held liable for the cost of those continued benefits if the State fair hearing decision upholds the MCO's or PIHP's action.

Finally, at proposed §438.408(f) (this paragraph was erroneously codified as a second paragraph (c), an error that has been corrected in this final rule), we outlined the requirements for State fair hearings. We required the State to permit the enrollee to request a State fair hearing within a reasonable time period specified by the State, but not less than 20 days or in excess of 90 days from the date of the MCO's or PIHP's notice of resolution (if the State requires exhaustion of the MCO or PIHP level appeal procedures) or from the date on the MCO's or PIHP's notice of action (if the State does not require exhaustion and the enrollee appeals directly to the State for a fair hearing). We also felt it was important to outline at proposed §438.408(f)(2) that the parties to the State fair hearing include the MCO or PIHP as well as the enrollee and his or her representative, or the representative of a deceased enrollee's estate.

Comment: Several commenters felt that proposed §438.408(a) should be revised to require that all notices of dispositions of grievances be provided in writing. These commenters argued that MCOs and PIHPs often confuse cases which should be treated as a grievance with those that should be handled as an appeal. Written dispositions of grievances would in the views of these commenters provide a mechanism for addressing this issue by revealing whether or not an MCO or PIHP is resolving a dispute pursuant to the appropriate mechanism.

Response: We believe that §438.408 makes the difference between a grievance and an appeal very clear. An appeal is triggered through an action, while a grievance

involves any dissatisfaction other than an action. If a State chooses to monitor its MCOs and PIHPs by requiring written notices, it may do so. However, we see no reason to require a written notice at the Federal level for all grievances, when many may not be of a nature for which such a notice is appropriate, and there is no Federal right to review by the State of such matters.

Comment: Comments on timeframes widely differed. Many commenters questioned the fact that the timeframes for appeals in the proposed rule were longer than those in place under Medicaid fee-for-service, Medicare+Choice, and versions of Patients Bill or Rights legislation. The commenters apparently believed that departing from these standards failed to adequately protect beneficiaries, and raised constitutional due process questions. These commenters wanted standard internal appeals to be resolved within 30 days. However, several other commenters found the 45-day timeframe more reasonable. Still other commenters were confused about the timeframes in general, and wanted an explanation of how they worked.

Response: We realize that the proposed timeframes were confusing as proposed, and potentially would not give the State a reasonable amount of time--or under some scenarios, any time, to conduct a fair hearing. We believe that after an MCO or PIHP takes up to 45 days, plus a possible 14-day extension, to make a decision, the 90-day clock for a fair hearing decision should stop during the time the enrollee takes to file for a State fair hearing (which could be as long as 90 days itself). Therefore, in response to the above comments, we have clarified in §431.244(f) that the State is required to resolve the State fair hearing within 90 days of the day the MCO or PIHP received the appeal, not

including the number of days the enrollee took to subsequently file for a State fair hearing. We believe that this is a reasonable timeframe because it holds the State accountable within a 90-day timeframe as long as the enrollee takes prompt action to follow up any denial at the internal appeal level. This will guarantee a high level of commitment on both sides. We also believe that 45 days is a reasonable standard timeframe for an MCO or PIHPs, because an enrollee may request an expedited appeal if he or she feels that a standard timeframe could jeopardize his or her health. With respect to the comments raising constitutional due process issues, we believe that applying this timeframe in this situation is fully consistent with due process requirements.

Comment: Some commenters noted that most States already have a complex grievance system in place, with specified timeframes and other rules, and changing these requirements may be confusing for beneficiaries and may not provide any additional protections to enrollees. These commenters asked us to permit "deeming" of compliance with Medicaid rules when the State's system met certain standards.

Response: The grievance and appeals requirements in §438.408 set forth minimum standards that MCOs, PIHPs, and States must follow. As long as those standards are met, a State is free to tailor those to the system it operates. We believe that these timeframes, notice requirements, and other standards grant States flexibility (e.g., the State is granted the discretion to establish timeframes, within ranges), and constitute the minimum necessary to ensure reasonable beneficiary protections. We strongly

believe that the established timeframes give States, MCOs and PIHPs adequate time to make an informed decision for enrollees at both the internal and State fair hearing levels.

Comment: Several commenters believed that the mandatory timeframes for the grievance and appeals process in §438.408 might be difficult to meet if enrollees fail to submit timely information, or are not available for an in-person presentation to the MCO or PIHP. These commenters asked that a limit be placed on the number of days MCOs and PIHPs are responsible for providing continued services pending a final determination in the case of an appeal from a termination of benefits. Some commenters wanted the timeframes to begin when all documentation is received from providers, rather than the date of notice of the action being appealed, for fear that the timeframes would be impossible to meet in certain cases.

Response: We believe that the timeframes in §438.408 will result in timely decisions based on all necessary evidence in the vast majority of cases. Enrollees have a strong incentive to cooperate fully with officials in an internal appeals process to facilitate timely coverage decisions. However, if some enrollees do not provide enough information to support their appeal, the MCO or PIHP is responsible for deciding the appeal on the basis of available information within the timeframes set out. Since continuation of benefits for authorized services being terminated may, at the beneficiary's request, continue throughout the appeals process until the final decision is made at the MCO, PIHP, or State level, we believe that it is reasonable to require MCOs and PIHPs

to make decisions within the specified timeframes so they are not responsible for covering benefits due to another party's delay.

Comment: One commenter felt that the timeliness for grievance and fair hearing completions may be difficult to meet in the case of mental health enrollees. The commenter inquired as to whether decisions on an action could be made retroactively, still comply with the requirements.

Response: The timeframe for filing an appeal in a State will be between 20 and 90 days, as determined by that State. We believe that this should be sufficient time for all enrollees to request a hearing. MCO, PIHPs, and States are then responsible for assisting enrollees with any procedural barriers they may encounter. Once the appeal is filed, the MCO, PIHP, or State is responsible for ensuring that a fair decision is made within the mandated timeframes.

Comment: A few commenters noted that in proposed §438.408, the paragraph titled "Requirements for a State fair hearing," which was identified in the preamble as paragraph (f), was inadvertently labeled paragraph (c) in the regulations text. The commenter assumed this was a typographical error.

Response: We agree with the commenter, and as noted above, we have made the appropriate change in §438.408.

6. Expedited resolution of appeals (Proposed §438.410)

In proposed §438.410 we required each MCO and PIHP to establish and maintain an expedited review process for appeals when the MCO or PIHP determines or the provider indicates that taking the time for a standard resolution could seriously jeopardize

the enrollee's life or health or ability to attain, maintain, or regain maximum function. Further, the MCO or PIHP was required under proposed §438.410(b) to ensure that no punitive action is threatened or taken against a provider who requests an expedited resolution, or supports an enrollee's request for an expedited appeal.

If the MCO or PIHP denies a request for expedited resolution of an appeal, it would be required under proposed §438.410(c) to transfer the appeal to the standard resolution timeframe in accordance with proposed §438.408(b)(2), and give the enrollee prompt oral notice of the denial following within two calendar days with a written notice.

Comment: One commenter contended that the definition of "expedited authorization decisions" can be applied to nearly any medical necessity determination. This commenter recommend removing language related to the "enrollee's ability to attain, maintain, or regain maximum function . . . could be jeopardized."

Response: We disagree with the commenter. If a standard appeals process is long enough to place an enrollee's health in jeopardy based on the definition above, we believe that an expedited appeal is warranted. Furthermore, the provider, MCO, PIHP, or State has the final decision on whether or not that threshold has been met. Therefore, we believe that it does not add any unwarranted administrative burden to MCOs, PIHPs, or States during the process.

Comment: Comments on the timeframes in proposed §438.410 again differed widely. Many commenters (again citing due process concerns and comparing the timeframes to other situations) wanted expedited internal appeals to be resolved within 72 hours, mirroring Medicare+Choice and State fair hearing timeframes.

However, several commenters found the timeframes unreasonable, unrealistic, subjective, and too prescriptive, and asked for more State flexibility to set timeframes. Some wanted the expedited process to be longer, such as a minimum of five working days, arguing that the present timeframe was unworkable. One commenter noted that most States already have timeframes, and suggested that changing these requirements may be confusing for beneficiaries while not providing any additional meaningful protections to enrollees.

Response: We continue to believe that the regulation should establish timeframes for steps in the internal appeal process, and that an expedited timeframe is necessary when the use of standard timeframes may jeopardize the enrollee's health. An expedited timeframe is an important beneficiary protection and ensures that those enrollees who need a quick decision will receive one. However, we believe that three working days for an expedited internal appeal makes the most sense. It provides for a very timely decision for those enrollees whose health may be in jeopardy, yet facilitates MCOs and PIHPs with the difficulty of operating during weekends and holidays. If an enrollee's health is jeopardized by an emergency medical condition, as defined in §438.114(a), then he or she would go to the nearest emergency room. In §438.408(a) we provide for States to establish timeframes that may not exceed the timeframes specified in this final rule. Thus, States may establish shorter timeframes. Again, with respect to the commenter's due process concerns, we are unaware of any legal basis for the suggestion that these regulations would violate due process.

Comment: Several commenters suggested that the regulations expressly allow the beneficiary to obtain an expedited review based on their primary care provider's opinion that the standard for expedited review has been met. They believed that MCOs and PIHPs should not be given complete control over the situation, because their financial arrangements may provide an incentive to deny services.

Response: Under §438.410(a), an MCO or PIHP must provide expedited review if it determines the standard for such review has been met, in the case of a request by an enrollee or if "the provider" makes such a determination. The preamble to the proposed rule did not specify whether "the provider" included the enrollee's primary care provider, or only the provider who would be furnishing the service requested in connection with the appeal. In response to this comment, we are clarifying that "the provider," as used in §438.410(a), refers to the provider of the services requested, since this provider is in the best position to evaluate the enrollee's need for those services. In some cases, this may be the primary care provider, in which case the current regulations would provide for the result the commenter seeks. In other cases, however, the primary care provider's opinion would not be dispositive of whether expedited review would be granted. We assume that the primary care provider's views would be taken into account by the MCO or PIHP in making their determination, or by "the provider" of the services sought, in deciding whether to request review or support the enrollee's request as provided in §438.410(a). If an enrollee disagrees with the MCO's or PIHP's decision, and the provider who would be furnishing the services does not support the enrollee's request, nothing prevents him or her from contacting the State and asking for its involvement or assistance. Furthermore,

States have the option to make a primary care provider's decision binding in all cases as part of their contract requirements, or State law, if they choose.

Comment: Several commenters were concerned about the MCO's and PIHP's ability to extend the 3-day expedited timeframe for 14 more days in cases in which this extension was not requested by the enrollee, and with the fact that the enrollee does not have the right to appeal such an extension. These commenters argued that the State has no mechanism for knowing that an MCO or PIHP has given itself such an extension, making the expedited provision arguably an empty mechanism. Furthermore, it appears to these commenters that the MCO or PIHP could give itself extensions indefinitely because there is no requirement to resolve the appeal after the first extension. They recommended only allowing an extension in these cases if the enrollee requests it.

Response: We partially disagree with the commenters' interpretation of the regulation. We state in §438.408(b)(3) that an MCO or PIHP may extend the timeframe of 3 working days up to an additional 14 calendar days. This is intended to be the outer time limit before a decision is made or the enrollee is eligible to file for a State fair hearing. Thus, an MCO or PIHP could not continue "indefinitely" to grant additional 14 day extensions. With respect to cases in which an enrollee does not request the extension, the extension still must be in the enrollee's interests, and an enrollee is free to argue to the State that this standard has not been met. The State then may decide if it should intervene. Moreover, we note that States have the option in contracts or in State law of permitting extensions only when requested by the enrollee.

Comment: One commenter expressed concern regarding the logistics of requiring MCOs and PHPs to give prompt oral notice to an enrollee of any denial of an expedited request. They noted that some Medicaid enrollees may not be accessible by telephone.

Response: We are aware that some Medicaid enrollees may not have telephones, and that it therefore may be difficult in some cases to provide oral notice. Therefore, in response to this comment, we have revised §438.410(c)(2) by requiring MCOs and PIHPs to make reasonable efforts to notify enrollees orally of decisions not to expedite an appeal, and to follow up with a written notice within two calendar days. MCOs and PIHPs should request information from enrollees about how and where they can be contacted.

Comment: Several commenters recommended that the State Medicaid agency be permitted 3 working days to hear expedited appeals that they receive, rather than 72 hours.

Response: We agree with the commenters. In response to this comment, the final rule, at §431.244(f)(2) and (3), now requires the State to conduct a fair hearing and make its decision within 3 working days for service authorization denials that meet the criteria for expeditious handling. We have chosen to use the same 3-working-days standard that applies to MCO or PIHP review in expedited cases so that the State would not be required to complete review of all expedited cases during weekends or holidays.

Comment: Many commenters advocated a requirement that expedited internal appeals not decided wholly in the enrollee's favor be automatically forwarded to the State

fair hearing process. These commenters felt that timing during an expedited process was essential, and that automatic forwarding would provide necessary speed to the process.

Response: We disagree with the commenters. We believe that the burden on MCOs, PIHPs and States, of automatic forwarding of appeal materials even in cases in which the enrollee may not wish to pursue a further appeal outweighs any benefits that might be achieved by such a policy. As in the case of when a beneficiary files an appeal during the 90 standard timeframe, it is reasonable to expect any enrollee who is seeking a particular service or benefit to promptly file for a State fair hearing if he or she is not wholly successful at the internal appeals level. We do not believe this would significantly add to the time it takes to handle the appeal. We note that the MCO or PIHP must give enrollees reasonable assistance in completing forms and taking other procedural steps.

Comment: One commenter noted that the proposed rule did not grant enrollees a right to a State fair hearing for an enrollee whose request for an expedited resolution is denied. Specifically, the commenter noted that this was not listed among the bases for a State fair hearing. The commenter wanted clarification on this point.

Response: The omission of a denial of a request for an expedited hearing from the ground for a fair hearing was intentional. As noted above, if a request for an expedited resolution is denied, the case is automatically treated as a standard appeal. However, if that internal appeal is not resolved wholly in favor of the enrollee, then the enrollee has a right to a State fair hearing.

Comment: One commenter objected to the fact that the proposed rule did not include a requirement for an expedited review process for grievances. They argued that this would be dangerous for enrollees with severe health problems who could not wait for the time frame of the standard review process.

Response: A grievance involves any dispute other than an “action.” Only an action should involve the possibility of a delay putting an enrollee with severe health problems at risk. We have an expedited provision for those type of disputes. Therefore, we do not believe that an expedited grievance process is a necessary mandate at the Federal level.

Comment: One commenter noted that proposed §438.410(a) should have a period at the end rather than a semi-colon.

Response: We agree with the commenter, and we made the appropriate change in §438.410(a) the final regulation.

7. Information about the grievance system to providers and subcontractors

(Proposed §438.414)

Proposed §438.414 required that the MCO or PIHP must provide the information specified at §438.10(g)(1) about the grievance system to all providers and subcontractors at the time they enter into a contract.

Comment: One commenter requested that CMS require that information about the grievance system be provided to subcontractors as well as to contracting providers.

Response: Proposed §438.414, which is unchanged in this final rule, already provided that this information must be provided to providers "and subcontractors."

8. Recordkeeping and reporting requirements (Proposed §438.416)

Proposed §438.416 required the State to require MCOs and PIHPs to maintain records of grievances and appeals and review the information as part of the State quality strategy.

Comment: Commenters urged that the regulation require States to provide members of the public, upon request, with MCO and PIHP summaries of grievance and appeal logs.

Response: States have the authority to require that MCOs and PIHPs make available to the State, or at the State's option, to members of the public, grievance and appeal logs or other MCO and PIHP grievance system documents. We do not agree that we should mandate this, however. In some cases, raw appeals data may be confusing to the public, or potentially misleading. We believe States are in the best position to decide how such information should be presented to the public. In designing their quality strategies, States should consider what information they and the public will need to support those strategies.

9. Continuation of benefits when an MCO or PIHP appeal of a termination, suspension, or reduction, and State fair hearing on such an action, are pending (Proposed §438.420)

Proposed §438.420 required that when the dispute involves the termination, suspension, or reduction of a previously authorized course of treatment, the MCO or PIHP must continue the enrollee's benefits until issuance of the final appeal decision or State fair hearing decision, if all of the following occur:

- The enrollee or the provider files the appeal timely.
- The services were ordered by an authorized provider.
- The period covered by the authorization has not expired.
- The enrollee requests such an extension of benefits.

We specified that timely filing means filing on or before the later of either the expiration of the timeframe specified by the State (in accordance with §438.404(c)(2)) and communicated in the notice of action or the intended effective date of the MCO's or PIHP's proposed action.

This provision would apply only when the MCO or PIHP physician initially authorized the services (that is, it would not apply to pre-service authorization requests that were denied) and when the beneficiary requests the services be continued (that is, the mere action of filing for an appeal or State fair hearing in a timely manner is not sufficient for benefits to be continued). The continuation of benefits provision would not require a further statement of authorization from the MCO or PIHP physician or affect benefits not originally authorized.

If the MCO or PIHP continues or reinstates the enrollee's benefits while the appeal is pending, under proposed §438.420(c), the benefits must be continued until one of the following occurs:

- The enrollee withdraws the appeal.
- The MCO or PIHP resolves the appeal against the enrollee, unless the enrollee has requested a State fair hearing with continuation of benefits until a State fair hearing decision is reached.

- A State fair hearing officer issues a hearing decision adverse to the enrollee.

Beneficiaries who have received continuation of benefits while they appeal to the MCO or PIHP are not obligated to pursue their appeal further, through the State fair hearing process, if the MCO or PIHP denies their appeal. It remains the beneficiaries' choice. It is important to note, however, that enrollees who lose their appeal at either the MCO, PIHP or State fair hearing levels will be liable for the costs of all appealed services from the later of the effective date of the notice of intended action or the date of the timely-filed appeal, through the date of the denial of the appeal. As a result, in §438.420(d), we proposed that if the final resolution of the appeal is adverse to the enrollee (that is, it upholds the MCO's or PIHP's action) the MCO or PIHP may recover the cost of the services furnished to the enrollee while the appeal was pending, to the extent that they were furnished solely because of the requirements of this section, and in accordance with §431.230(b).

Comment: Many commenters pointed out that the proposed rule does not specify all the same circumstances set forth in §§431.230 and 430.231 as situations in which benefits must be continued or reinstated. These commenters specifically cited advanced notice requirements, and argued that this rewards MCOs and PIHPs that do not provide advanced notice.

Response: We disagree with the commenters. MCOs, PIHPs, and States have a strong incentive to notify enrollees timely of any reduction, limitation, or suspension of existing services. While enrollees have to actively request continuation of benefits while filing an appeal, they must be given the opportunity to do so before the benefits are

reduced, limited, or suspended. And since enrollees have this right until an adverse State fair hearing decision (assuming of course that he or she follows the applicable rules), a delay in notice only gives enrollees benefits for a longer period of time. However, in response to this comment, we now state in the regulation text that the enrollee has 10 days after the MCO or PIHP mails the notice of action to request continuation of benefits. Therefore, even if the effective date of action has passed, an MCO or PIHP may not discontinue those benefits until 10 days after the notice is mailed. We believe that this sufficiently addresses the commenters' concern.

Comment: We received many comments regarding enrollees' rights to continuation of benefits during the MCO and PIHP appeal process. Several commenters thought that the regulations mandate that MCOs and PIHPs continue benefits in all cases in which the appeal involves services that are being terminated or reduced. Several commenters felt that continuation of benefits pending resolution of an appeal or State fair hearing, without financial risk, is one of the most important protections needed for managed care enrollees.

In contrast, several other commenters were opposed to extending continuation of benefits requirements to the MCO and PIHP appeal process. One commenter contended that this requirement would have significant cost implications for MCOs and PIHPs. Another commenter felt that benefits should be continued only at the point when an enrollee requests a State fair hearing.

One commenter thought that requiring MCOs and PHPs to continue benefits would place them in an untenable position with their providers, compromising their

ability to manage care and cost. This commenter expressed concern that this provision may damage managed care programs, and believed it was unnecessary, given the requirement of expedited review of appeals in cases in which a delay could jeopardize health.

Response: Because we allow States to require exhaustion of the MCO and PIHP appeal before receiving a State fair hearing, we believe that, in order for the right to continued benefits during a State fair hearing to be meaningful, continuation of benefits must begin with the filing of an MCO or PIHP appeal, and continue until the State fair hearing decision. Given that, with few exceptions, the overall 90-day timeframe for a final fair hearing decision applies even when exhaustion is required, the amount of time benefits must be continued is the same under this final rule as under the longstanding fair hearing system. Continuation of benefits at the MCO and PIHP level thus is part of the same longstanding right to continuation of benefits that has existed for Medicaid beneficiaries when services are reduced or terminated.

As in fee-for-service, under managed care, the right to continuation of benefits is not exercised without financial risk to the beneficiary of payment for services provided should he or she lose the appeal. Otherwise, MCOs, PIHPs, or States would be unfairly liable for treatment in which they were correct in limiting, reducing, or suspending. It is because of this potential risk for enrollees that we require that the enrollee specifically request continuation of benefits. Under §438.404(b)(7), the notice of adverse action must include an explanation of this choice.

While expedited appeals will decrease the amount of time MCOs and PIHPs are liable to continue benefits for enrollees with pending appeals, the expedited appeal process does not substitute for the protection provided to Medicaid beneficiaries of the right to continuation of previously authorized benefits pending the outcome of a State fair hearing decision.

If the benefit is a Medicaid covered service, but not an MCO or PIHP covered service, the State, not the MCO or PIHP is responsible for providing those services pending the outcome of the State fair hearing.

Comment: Several commenters requested that §438.420 should clearly state that re-authorization of a service at a lower level than previously received, or a denial of re-authorization, is a termination or reduction of the service requiring the continuation of benefits pending appeal. Other commenters requested that we make clear in the regulation text that continuation of benefits does not include the expiration of an approved number of visits through an authorized course of treatment.

Response: As noted above, we agree that the expiration of an approved number of visits does not constitute a termination for purposes of notice and continuation of benefits. If an enrollee requests re-authorization for services and the MCO or PIHP denies the request or re-authorizes the services at a lower level than requested, the MCO or PIHP must treat this request as a new service authorization request and provide notice of the denial. We have explained above that the language in the proposed rule already limited the right to continued benefits to services that were authorized. In response to this comment, in order to make clear that the continuation of benefits itself is not what we

mean by "authorized," we have revised §438.420(b)(4) by adding the word "original" to make clear that benefits are only continued to the extent they were originally authorized. As noted above, we also have added a new §438.420(c)(4) in this final rule to make clear that when benefits are continued under §438.420(b), they may be discontinued when the original authorization expires.

Comment: One commenter was concerned about the status of enrollees who received authorization for a course of treatment from a non-network physician but then had those benefits limited by a new MCO once the course of treatment had begun. They believe that these enrollees need protection for their benefits.

Response: An enrollee who has his or her existing benefits reduced, limited, or suspended by an MCO, PIHP, or State has the right to request a continuation of benefits regardless of the source as long as it originated from a Medicaid participating provider. It is the State's decision as to what entity is liable for those benefits during the appeals process.

Comment: One commenter argued that discontinuing services being provided by an MCO without a State fair hearing was unconstitutional.

Response: We do not believe that we need reach constitutional issues (such as, regarding whether a property interest or State action exist) because Medicaid beneficiary rights are directly addressed in section 1902(a)(3) and 1932(b)(4), and it is these statutory rights that are implemented in this final rule. As noted above, we believe that if services are discontinued on the date the authorization expires, this is not a "termination" of services that the enrollee had any right to expect to receive, and thus is not a termination

within the meaning of section 1902(a)(3) and the implementing regulations. In the case of a termination of authorized services prior to the expiration date of the authorization, we agree with the commenter that a beneficiary should have the right to have these benefits continue pending a hearing on the termination. We provide the enrollee with 10 days to request to have benefits continue under these circumstances, pending an appeal and State fair hearing. We believe that this process is fully consistent with the Medicaid statute and constitutional requirements, to the extent applicable.

Comment: Several commenters requested that we delete the requirement that the beneficiary must request continued benefits. They contended that this requirement was constitutionally defective in that they believed continued benefits, without pre-requisites to obtaining them, to be required under due process.

The commenters noted that while the existing regulation at §431.230(b) provides for the possibility of recoupment, benefits are continued when an appeal is filed timely. The commenters found no reason to change this long-standing rule for beneficiaries who are receiving services through an MCO or PIHP. Also, several commenters believed that proposed §438.420(c)(2) made it impossible for benefits to continue through a State fair hearing, because a beneficiary would have had to file for a State fair hearing before the MCO or PIHP had even made its internal appeal decision in order for benefits to continue.

Response: Again, we do not believe we need reach constitutional issues here, but that the final rule as proposed is fully consistent with any applicable constitutional requirements. It is not true that benefits continue under fee-for-service Medicaid

"without pre-requisites to obtaining them." Benefits only continue under fee-for-service if the beneficiary timely files an appeal. We do not see the difference between requiring the filing of an appeal for benefits to continue and requiring that as part of such an appeal, the beneficiary request that benefits continue. Indeed, given the possibility of beneficiary liability in both cases, we believe that the approach in this final rule is more protective of beneficiary rights. Under this rule, after an action, the beneficiary will be notified both of this right to continuation of benefits and the possible liability for services if the final decision is not in his or her favor. Thus, we believe the general concern about continued benefits not being automatic with an appeal is unfounded.

However, we agree with the concerns expressed by several commenters' that proposed §438.420(c)(2) could make it impossible for benefits to continue through a State fair hearing as proposed. Therefore, in response to these comments, we have revised §438.420(c)(2) by requiring beneficiaries to re-request continuation of benefits within 10 days after the mailing of the internal appeal decision against the enrollee, in order to preserve continuation of benefits during a State fair hearing.

10. Effectuation of Reversed Appeal Resolutions (Proposed §438.424)

Proposed §438.424 required that if the MCO, PIHP, or the State fair hearing officer reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the MCO or PIHP must authorize or provide the disputed services promptly, and as expeditiously as the enrollee's health condition requires. Furthermore, if the MCO, PIHP, or the State fair hearing officer reverses a decision to deny authorization of services, and the enrollee received the disputed services while the

appeal was pending, the MCO, PIHP, or the State would be required to pay for those services, in accordance with State policy and regulations.

Comment: Many commenters supported a time frame of no more than 10 days for an MCO or PIHP to provide or pay for services subsequent to a State fair hearing because enrollees with successful appeals should not have to adjudicate over the word “promptly.”

Response: We disagree that MCOs and PIHPs should be held to a Federal timeframe to provide or pay for services, because such a timeframe may not be reasonable in the case of the circumstances of all States. Consistent with the State fair hearing policy in §431.246, we are requiring that the services are provided promptly, or as expeditiously as the enrollee’s health condition requires. We believe that the States are in the best position to decide whether to require specific time limits if they choose.