§ 302.6 Notification requirements.

* * * * *

(e) * * *

(3) Releases to the air of any hazardous substance from animal waste at farms.

* * * * *

PART 355—EMERGENCY PLANNING AND NOTIFICATION

4. The authority citation for part 355 continues to read as follows:

Authority: 42 U.S.C. 11002, 11004, and 11048.

5. Section 355.20 is amended by adding in alphabetical order the definitions of ''Animal waste'' and ''Farm'' to read as follows:

§ 355.20 Definitions.

* * * * *

Animal Waste as used in § 355.40 only, animal waste means manure (feces, urine, other excrement, and bedding, produced by livestock that has not been composted), digestive emissions, and urea. The definition includes animal waste when mixed or commingled with bedding, compost, feed, soil and other typical materials found with animal waste.

* * * * *

Farm as used in § 355.40 only, farm means:

(1) Any place whose operation is agricultural and from which $1,000 or more of agricultural products were produced and sold, or normally would have been sold, during the census year. Operations receiving $1,000 or more in Federal government payments are counted as farms, even if they have no sales and otherwise lack the potential to have $1,000 or more in sales; or

(2) A Federal or state poultry, swine, dairy or livestock research farm.

* * * * *

6. Section 355.40 is amended by adding paragraph (a)(2)(viii) to read as follows:

§ 355.40 Emergency release notification.

(a) * * *

(2) * * *

(viii) Any release to the air of a hazardous substance from animal waste at farms.

* * * * *

[FR Doc. E7–25231 Filed 12–27–07; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

42 CFR Parts 422, 423, and 498

Office of the Inspector General

42 CFR Part 1005

Office of the Secretary

45 CFR Parts 16, 81, 160 and 1303

RIN 0991–AB42

Revisions to Procedures for the Departmental Appeals Board and Other Departmental Hearings

AGENCY: Office of the Secretary, Centers for Medicare and Medicaid Services, HHS.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Department of Health and Human Services (Department) proposes to amend Departmental regulations governing administrative review by the Departmental Appeals Board (DAB) and certain other administrative review regulations to ensure that the final administrative decision of the Department reflects the considered opinion of the Secretary of Health and Human Services (Secretary). Current regulations at 45 CFR Part 16 governing the review of grant disputes do not specifically require the DAB to follow published guidance issued by the Secretary or a Departmental component. The DAB decision is currently the final administrative decision of the Department on such disputes and currently there is no Secretarial review of this final decision. Similarly, the DAB currently provides the final agency review of the imposition of civil monetary penalties (CMPs) for which administrative appeal is available under 45 CFR Part 160, Subpart E, enforcement sanctions under 42 CFR Part 422 and 423, determinations subject to reconsideration and appeal under 42 CFR Part 498 and the imposition by the Inspector General of the Department (I.G.) or the Centers for Medicare and Medicaid Services (CMS) of exclusions, CMPs and assessments subject to appeal under 42 CFR Part 1005. As in 45 CFR Part 16, the decisions of the DAB under these processes are considered the final agency action on matters, though they are not subject to Secretarial review.

This proposed rule would amend DAB regulations to require that the DAB follow published guidance that is not inconsistent with applicable statutes and regulations and would permit the Secretary an opportunity to review DAB decisions to correct errors in the application of law, or deviations from published guidance, in such disputes. This proposed rule would make technical changes to the regulations at 45 CFR Part 16. This proposed rule would also amend hearing and appeal procedures at 45 CFR Part 160, Subpart E and at 42 CFR Parts 422, 423 and 498 to include a parallel statement regarding the treatment of published guidance. Similarly, this proposed rule would amend the procedures at 45 CFR Part 81 to provide a similar statement regarding the treatment of published guidance by hearing examiners and reviewing authorities. In addition, this proposed rule would amend the hearing and appeal procedures at 45 CFR Part 160, Subpart E and 42 CFR Parts 422, 423, 498 and 1005 to provide a parallel opportunity for Secretarial review of DAB decisions. Finally, this proposed rule would revise the procedures for Head Start grantee appeals by applying the current 60-day time limit for ''final decisions'' to the Board's decision.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 28, 2008.

ADDRESSES: You may submit comments either by E-mail to *randolph.pate@hhs.gov* or by mail to: Randy Pate, 200 Independence Ave., SW., Room 415F, Washington, DC 20201.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT: Randy Pate, 202–690–7858.

SUPPLEMENTARY INFORMATION:

I. Background

HHS was the first federal grantor agency to offer a structured process of administrative dispute resolution for its grantees on a large scale, when, in 1973, it established what was then called the Departmental Grant Appeals Board. The name was changed to the Departmental Appeals Board (DAB) when, as noted below, the jurisdiction was significantly expanded. The name ''Departmental Appeals Board'' is now used to refer to two entities: (1) the decision-making body consisting of Board Members, appointed by the Secretary, who issue decisions made by panels of three Board Members; and (2) in general, the larger organization, which is located in the Office of the Secretary and which includes not only the Board, but also

Administrative Law Judges (ALJs), Administrative Appeals Judges who serve on the Medicare Appeals Council, and organizational divisions that support the Board Members and Judges, and perform other organizational functions. Below, we use the term ''Board'' to refer to the decision-making body and the acronym ''DAB'' to refer to the larger organization.

The current rules for the Board, at 45 CFR Part 16, were issued on August 31, 1981, at 46 FR 43818. Those rules set out a fair, quick and flexible process for appeal from final written decisions. The rules provide a framework which has been used by the Department for resolution of an increasing range of disputes.

The basic jurisdiction of the Board over grant disputes is described in Appendix A to the current regulations at 45 CFR Part 16. This jurisdiction is exercised by the Board Members, with support from the Appellate Division of the DAB. The Board also has appellate jurisdiction over disputes that are heard by Administrative Law Judges (ALJs) who, in most cases, are assigned to the DAB and supported by the Civil Remedies Division of the DAB. These ALJ hearings are conducted pursuant to separate regulatory provisions, but ALJ decisions are subject to review by the Board. In 1988, the Secretary delegated to the DAB responsibility for adjudicating civil money penalties and exclusions imposed under a wide range of fraud and abuse authorities. In 1993, the Secretary delegated to the DAB responsibility for hearing appeals in provider and supplier participation, enrollment and enforcement cases brought by CMS. Also, when the Social Security Administration (SSA) became an independent agency in 1995, the Secretary delegated to the Board Chair the Medicare Appeals Council function of hearing appeals in Medicare coverage, payment and entitlement cases.

The DAB has final review authority over the reconsideration and appeal process for determinations under 42 CFR Part 498. These are procedures for reviewing certain specified initial determinations, which include those that affect participation in the Medicare and Medicaid programs, impose sanctions on certain providers, and impose enforcement remedies on laboratories under both Medicare and the Clinical Laboratories Improvement Amendments of 1988. Under these procedures, providers or suppliers generally have a right to a hearing before an ALJ, and a review of the ALJ decision by the Board. When this process was first established, by final rule published at 33 FR 7317 (May 17, 1968), the final review was vested in the Appeals Council of the Social Security Administration, which was then a component agency of this Department. Final review authority was transferred to the DAB after the SSA became an independent agency. 61 FR 32347 (June 24, 1996).

The DAB has final review authority under 42 CFR Part 1005 over disputes concerning the imposition of exclusions, CMPs, and assessments relating to health care fraud and abuse under sections 1128 and 1128A of the Social Security Act as well as other disputes. CMS and the I.G. have been delegated the authority by the Secretary to administer these health care fraud and abuse authorities, as described in 42 CFR Parts 402, 1001, 1003, and 1005. As provided in 42 CFR Part 1005, disputes concerning the exercise of these authorities are heard by an ALJ, and the decision of the ALJ may be appealed to the DAB. Under these regulations, the scope of ALJ and DAB review is limited.

The DAB has review authority concerning Medicare Local Coverage Determinations (LCDs) and National Coverage Determinations (NCDs) pursuant to section 1869(f)(1) of the Social Security Act and to regulations at 42 CFR Part 426. Challenges to LCDs are heard initially by ALJs, with a statutory right of appeal to the Board, and challenges to NCDs are heard by the DAB directly. This proposed rule would not affect the LCD or NCD review authority.

Under 45 CFR Part 150, ALJs of the DAB provide hearings concerning the imposition of civil money penalties by CMS against health insurance issuers and non-federal governmental plans for failure to comply with requirements of title XXVII of the Public Health Service Act and with regulations at 45 CFR Parts 146 and 148 (''HIPAA portability requirements''). This proposed rule would not affect these hearings, which are subject to review by the CMS Administrator.

On February 16, 2006, at 71 FR 8389, the Department issued final rules located in 45 CFR Part 160, Subpart E, providing for Board final review authority over disputes involving the imposition of civil money penalties for violation of the Administrative Simplification provisions of Title II of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations. These provisions contain standards for certain financial and administrative transactions, code sets, unique health identifiers and the security and privacy of certain health information. The authority for civil money penalties is contained in section 1176 of the Social Security Act, 42 U.S.C. 1320d–5, which at subparagraph (a)(2) provides an opportunity for administrative appeals, by incorporating by reference section 1128A of the Social Security Act, which includes the administrative hearing and appeals requirements set forth in section 1128A(c), 42 U.S.C. 1320a–7a.

On December 5, 2007, at 72 FR 68700, CMS issued final regulations at 42 CFR Parts 422 and 423 providing for appeals of civil money penalties imposed on Medicare Advantage organizations and Medicare prescription drug sponsors (based on a proposed rule issued May 25, 2007 at 72 FR 29368). These regulations provided for an opportunity for a hearing before an ALJ and review of the ALJ determination by the Board.

The DAB also exercises additional hearing and appeal responsibilities based on procedural delegations of authority. Such delegations can be made on a case-by-case basis, through a general delegation of authority over a class of disputes, or through other arrangements between the DAB and the Secretary or the head of the appropriate HHS operating division or other agency responsible for administering the program.

As the DAB's jurisdiction has increased, the issues for DAB review have grown in complexity and significance. In addition, the volume of cases has grown considerably. The DAB has responded to the challenges posed with considerable diligence and sophistication. In particular, Board members have developed great expertise in dispute resolution, hearing procedures, and many aspects of the subject Departmental programs.

The procedures used by the Board for grant disputes are broadly modeled after adversary judicial proceedings and have been successful in resolving factual disputes based on a record. Current rules, however, lack sufficient safeguards to avoid putting the DAB in a situation where it is prompted to substitute its judgment on interpretive issues for that of the Secretary or the delegated component with interpretive authority. While the Board has considerable expertise in Departmental programs, however, under the current rules, the Board does not have access to the full range of policy considerations that the Secretary and the relevant component may have in interpreting applicable statutes and regulations.

Similar considerations apply in the Board's appellate review of ALJ decisions concerning civil money penalties under 45 CFR Part 160, Subpart E, enforcement sanctions under

42 CFR Parts 422 and 423, review of initial determinations under 42 CFR Part 498, or review of ALJ decisions concerning civil remedies.

Current regulations at 42 CFR Parts 422, 423, and 498 do not specifically articulate the applicability of statutes, regulations, or published guidance. And the current procedures at 45 CFR Part 160, Subpart E, 42 CFR Part 498 and 42 CFR Part 1005 contain no provision for Secretarial review.

As a result, these hearing procedures do not provide sufficient safeguards to ensure that the decisions accurately reflect the considered views of the Secretary.

In addition to the Departmental hearing procedures discussed above, under 45 CFR Part 81, there are procedures governing administrative hearings pursuant to Title VI of the Civil Rights Act of 1964 and 45 CFR Part 80. These hearings are conducted by hearing examiners who are authorized, under § 81.62, either to make initial decisions or to recommend findings and propose decisions. These decisions are reviewable by a reviewing authority, under § 81.104, and by the Secretary, under § 81.106.

The hearing regulations in 45 CFR Part 81 do not clearly articulate the applicability of statutes, regulations or published guidance. Although the regulations can be read to imply that presiding officers and reviewing authorities will be bound by applicable statutes, regulations and guidance, there is no clear articulation of this standard. As a result, there is a possibility that decisions of presiding officers and reviewing authorities will not accurately reflect applicable law or policy.

II. Provisions of This Proposed Rule

This rule proposes substantive changes in the general DAB procedures at 45 CFR Part 16, and in the hearing and appeal procedures at 45 CFR Parts 81 and 160, Subpart E, 42 CFR Part 1005 and 42 CFR Part 498. The rule proposes to clarify that, in cases heard by the Board under the authority of 45 CFR Part 16, the Board must follow published guidance issued by the Secretary or relevant component to the extent the guidance is not inconsistent with applicable statutes and regulations. The rule proposes to provide an opportunity for Secretarial review (including, where the Secretary deems appropriate, remand) of Board decisions under 45 CFR Part 16. The rule would also amend 45 CFR Part 16 in several places to update the DAB's title, update the current mailing address, and remove certain outdated regulatory references. And the rule would amend Appendix A to 45 CFR Part 16 to clarify that the Board's authority to hear disputes may arise from a procedural delegation of authority directly from the Secretary or other responsible official. The rule additionally proposes to make conforming amendments to articulate the applicability of statutes, regulations and published guidance in hearing and appeals procedures under 45 CFR Part 81 and Part 160, Subpart E, and under 42 CFR Part 498. We would also provide an opportunity for Secretarial review of decisions under 45 CFR Part 160, Subpart E, and 42 CFR Parts 498 and 1005.

We anticipate that, unless there are statutory reasons to the contrary, future areas of DAB jurisdiction will incorporate similar review procedures. We also intend that each of the provisions of this DAB proposed rule will remain in force if any of the provisions are invalidated for any reason.

Any final rule based on this proposed rule would be effective prospectively only, and would not affect final decisions that have been issued by the Board prior to the effective date. The final rule would affect cases that are still under Board review as of the effective date of the final rule.

We address each of the modifications in this proposed rule individually below:

A. Applicability of statutes, regulations and published guidance (45 CFR § 16.14)

Current regulations at 45 CFR § 16.14 provide that the Board ''shall be bound by all applicable laws and regulations.'' This provision, however, does not address the weight to be afforded interpretations of statutes and regulations that have been adopted by the Secretary either directly or through the Departmental component with delegated authority to administer the program whose decision is the subject of Board review.

In this proposed rule, we clarify that the Board should follow published guidance of the Secretary or relevant component, to the extent not inconsistent with applicable statutes and regulations. This requirement would parallel the standard included at 45 CFR § 160.508(c)(1) of the final regulations recently issued governing appeals involving the imposition of civil money penalties for violations of the Administrative Simplification provisions under HIPAA and its implementing regulations. As we indicated in that rulemaking, by ''published guidance'' we mean to include guidance that has been publicly disseminated. 71 FR 8416. In this case, this includes, for example, guidance issued through manual provisions, State Medicaid Directors letters, or posting on the CMS Web site. While this would not include written statements that are issued to particular grantees, or in briefs filed by the respondent agency in litigation, we expect that the Board would give weight to such statements in the absence of contrary published guidance or conflicts with other agency statements, as an initial exercise of the interpretative authority delegated to the agency and an expression of the agency's policy expertise. This is particularly true with respect to issues of first impression. When there is no published guidance on an issue, or when there is ambiguity in the published guidance, we would expect the Board to review relevant unpublished issuances for direction in interpreting such an issue.

By ''relevant component'' we mean the Departmental component delegated responsibility for interpreting and administering the provision at issue. This would not necessarily be the component that is a party in the proceeding before the Board. For example, the issuances of a component operating a grant program would not be controlling with respect to interpretations of cost allocation requirements, since responsibility for interpreting such requirements is delegated to the Departmental Division of Cost Allocation. To make this clear, we are also providing that the Board will be bound by Secretarial delegations of authority.

This clarification would help to ensure that the decisions of the Board reflect the considered judgment of the Department on such issues. The proposed provision would explain that it is not the role of the Board to weigh the relative strengths of an interpretation adopted after due consideration of relevant factors by the Department or its components. The strength of regulatory and policy interpretations are necessarily considered in their adoption. It is the role of the Department and its components to craft regulations and adopt policy interpretations. In that process, the Department necessarily contemplates various policy alternatives and litigation risks. Those considerations are legitimately left to the discretion of the Department and its components rather than an adjudicative body like the Board. Because the Board was created as an adjudicator, separate and apart from the policy-making components of the Department, its role is important but limited. As the

Supreme Court has recognized, where a separate administrative adjudicatory body is created, its role is limited to finding facts and resolving individual disputes, but it is not authorized to develop new interpretive policies. Having the DAB substitute its policy views would limit the ability of the Department to determine the level of acceptable risk in light of program priorities and goals, and ultimately would limit Departmental flexibility in performing its functions.

We anticipate that this change would have greater effect in statutory entitlement programs than it would in discretionary grant programs. In certain discretionary grant programs, the requirements are neither statutory nor regulatory but are largely set by the grant award terms and conditions. These requirements are akin to contractual obligations. In these discretionary grant programs, the issue of notice to the grantee of a purported requirement may be the key issue in resolving disputes. The adequacy of the notice may depend on the specific grant documents applicable to the grant award. By contrast, in statutory entitlement programs, requirements are set in statute and regulation, and disputes focus on statutory and regulatory interpretation. In those instances, the DAB would be required to follow published guidance of the Secretary or the relevant component on the interpretive issue. Notice to the grantee generally would not be determinative in a statutory program since the applicable statute or regulation gives grantees notice of the scope of interpretive flexibility.

B. Secretarial Review of DAB Decisions Concerning Disputes (45 CFR 16.21)

The original rules of the Board provided for the relevant constituent component of the Department to review, modify, or reverse Board decisions before they became final decisions of the Secretary. 45 CFR 16.10 (1973); 38 FR 9907 (Apr. 20, 1973). In 1978, HHS's rules were modified so that the Board decisions would be ''final administrative decisions with respect to reconsideration of disallowances arising under various Federal-State public assistance programs.'' 43 FR 9264, 9264 (March 6, 1978). When the current Board grant review regulations were originally proposed on January 6, 1981, 46 FR 1644, there was a provision for Secretarial review of Board decisions. In the final rules, adopted on August 31, 1981, 46 FR 43816, that provision was omitted. The preamble to the final rule stated that numerous comments had been submitted on this issue, and that ''[t]he Department continues to study whether Board decisions should be 'final' or should be subject to Secretarial review.'' The preamble indicated that the omission of the provision for Secretarial review did not reflect a final decision on this issue, but was an interim measure ''to avoid further delay in implementing these procedures.''

Now, with over 20 years of experience, we are again proposing to authorize Secretarial review of Board decisions. This change is intended to ensure consistency in decision making and to ensure that the Secretary's policies are correctly implemented. Further, this proposed change is consistent with the rules originally establishing the Board for adjudication of grant disputes. While we intend that the instances of Secretarial review will be limited, the availability of such review is essential to ensure the accuracy of DAB decisions in reflecting the proper application of relevant statutes, regulations and interpretive policy. Such accuracy is important because Board decisions are binding on the Department in the case at hand, are considered final federal agency action for purposes of judicial review, and may have some precedential value for future adjudications. In cases of first impression, these decisions may be the first articulation of Departmental interpretation and implementation of policies with respect to applicable statutes and regulations. Only through review of DAB decisions can the Department exercise its full authority to interpret and implement statutory and regulatory provisions and ensure that the Secretary's policies are appropriately implemented. The Secretary's views will continue to be ultimately subject to federal court review.

We are proposing a clear time frame for the Secretary to determine whether to undertake review, so as not to unduly delay the administrative review process and the availability of judicial review. We believe 30 days should be sufficient time for the Secretary to determine whether review is warranted. We have not proposed any process for either party to request Secretarial review, and we do not anticipate that the Secretary or the delegated official performing the review would consider external requests for review.

We anticipate that Secretarial review will ordinarily be completed within a 45-day time frame after acceptance of review. In light of the varying complexity and significance of Board cases, however, we are not proposing to limit the time for Secretarial consideration. For example, additional time may be required in cases involving a voluminous record, or when additional development of the record is necessary.

After undertaking review, the Secretary would be authorized to affirm or reverse a Board decision, or to remand a case back to the Board for further consideration of identified errors in the application of statutes, regulations or interpretive policy. In cases where Secretarial review is undertaken, the original DAB decision would be regarded as a proposed decision, and would be set aside to the extent inconsistent with the Secretary's review decision.

In cases involving certain parts of title IV of the Social Security Act, the Secretary would only be authorized to affirm the Board or remand the case back to the Board with instructions for further consideration. This is because sections 410(c) and 1123A(c) of the Social Security Act, pertaining to the program for Temporary Assistance for Needy Families, provide that the final decision of the Board is appealable to federal court. In these cases, while we would provide for Secretarial review, the Board would issue the final agency decision.

We have not proposed in the regulatory text any briefing or other procedures for Secretarial review in order to maintain flexibility to tailor the process to the needs of the particular case. We anticipate that the Secretary would notify the parties as to the procedures to be followed. But we invite comments on whether the regulations should specify procedures for Secretarial review.

We propose to require that the Secretary would issue a written decision upon review. In the case of affirmance or reversal of the Board decision, this would be the final decision of the Secretary on the matter. The written decision would contain the basis for the Secretary's conclusions. In the case of a summary affirmance, or a partial affirmance, the written decision could incorporate by reference some or all of the Board decision. In the case of a remand of the case to the Board for further proceedings, the written remand order would include the basis for remand and would instruct the DAB in the proper application of statutes, regulations or interpretive policy. Upon remand, the Board would be bound by the Secretary's remand instructions. The Board would be responsible, however, to apply the law to the facts of the particular case. The Board would thus issue a new decision in accordance with the Secretary's instructions.

While we anticipate that Secretarial review will be a review of the record created before the Board, the Secretary may identify specific issues for which additional briefing by the parties is necessary. This additional briefing would ensure that the record fully reflects the factual, legal and policy issues that the Secretary considers in reviewing the case. Such additional briefing would ensure that both sides have a full and fair opportunity to respond to issues that the Secretary determines are relevant to the outcome. We do not presently contemplate providing the parties a right to request an additional briefing opportunity, but we solicit comments on whether there are circumstances in which such a right would be appropriate.

C. Technical Changes (45 CFR Part 16)

1. Title of 45 CFR Part 16, 45 CFR §§ 16.2 and 16.20(a)—Updating DAB Name and Address

We propose to delete the word ''Grant'' from the title of 45 CFR Part 16 and the definition of the ''Board'' in § 16.2, and to update the name and address of the DAB in § 16.20(a). In § 16.20(a), we would reference filing instructions set forth in the final written decision being appealed and the Appellate Division Practice Manual found on DAB's Web site. We indicate that the DAB's mailing address can be found on that Web site because the Web site can reflect updated addresses. We also list the 2007 address. In light of these references, we would delete § 16.20(d) and (e), since these provisions refer to issues addressed in the filing instructions noted in revised § 16.20(a) and, furthermore, do not reflect current Board procedures relating to electronic submissions.

2. 45 CFR §§ 16.3(b), 16.7(a), 16.12 and 16.22(b)(1)–Deleting Outdated References

45 CFR §§ 16.3(b), 16.7(a) and 16.22(b)(1) contain outdated references to sections of 45 CFR Part 74, which has since been revised so that the cited sections no longer correspond to the referenced substance. For example, the references to 45 CFR 74.304 in § 16.3(b) and 16.7(a) would more properly be to 45 CFR 74.90. We propose to delete these references both because they are outdated and because the regulations at 45 CFR Part 74 are general cross-cutting Departmental rules and many of the programs subject to review now have individualized regulatory provisions that address the same subjects, in some cases in more detail. 45 CFR 16.12(d) contains an outdated reference to the Public Health Service, which we would delete. Instead, we would insert a parenthetical reference to the process set forth at 42 CFR Part 50 as an example of a formal preliminary review process.

3. 45 CFR Part 16, Appendix A—Updating References and Reflecting Board Authority to Hear Disputes Based on Procedural Delegations of Authority

In Appendix A, we propose to update or delete outdated statutory and regulatory references. In addition, as noted above, the Board exercises hearing and appeal responsibilities based on procedural delegations of authority to the Board from the Secretary, the head of the appropriate HHS component responsible for administering the program. Such a delegation may be made on a case-by-case basis, through general delegations of authority over a class of disputes, or through other arrangements between the DAB and the Secretary or the head of the appropriate HHS component responsible for administering the program. The proposed rule would clarify Appendix A to make clear that the Board may hear cases based on such a delegation.

D. Addition of 45 CFR § 81.64—Conforming Changes in Standard of Review

Regulations in 45 CFR Part 81 set forth procedures for administrative hearings pursuant to Title VI of the Civil Rights Act of 1964 and 45 CFR Part 80. These hearings are conducted by hearing examiners who are authorized, under § 81.62, to either make initial decisions or recommended findings and proposed decisions. These decisions are reviewable by a reviewing authority, under § 81.104, and by the Secretary, under § 81.106.

The regulations governing these hearings and reviews, however, do not clearly articulate the standard of review to be applied by hearing examiners and reviewing authorities in reviewing issues of law, regulation or policy interpretation.

We are thus proposing to add a new section, § 81.64, to explain that hearing examiners and reviewing authorities are bound by all applicable statutes, regulations, Secretarial delegations of authority and published guidance and interpretations of the Secretary or relevant component to the extent not inconsistent with applicable statutes and regulations. This is the same standard, discussed above, that would be applied in DAB review under 45 CFR Part 16. This change would thus conform the standard of review in these hearings with the standard of review in other Departmental hearing procedures.

E. 45 CFR §§ 160.508(c), 160.548, and 160.554—Conforming Changes in Standard of Review, Removal of Board Decision Reconsideration Process and Provision for Secretarial Review Authority

Regulations at 45 CFR Part 160, Subpart E, set out procedures for administrative hearings for disputes involving the imposition of civil money penalties for violation of the Administrative Simplification provisions of HIPAA and its implementing regulations. Current regulations in 45 CFR § 160.508(c)(1) articulate limitations on ALJ review with respect to finding invalid or refusing to follow Federal statutes, regulations, or Secretarial delegations of authority, or refusing to defer to published Departmental guidance. While we believe these limitations embody the same principles as the limitations that we are proposing elsewhere in this rulemaking, we are proposing to revise slightly 45 CFR § 160.508(c)(1) to conform the description of these limitations to the other proposed regulatory provisions discussed in this rulemaking.

These limitations are also intended to apply to Board appellate review of the ALJ decisions. Accordingly, to make clear that these same limitations also apply to Board appellate review of ALJ decisions, we propose to add a provision to that effect at § 160.548(h)(2).

We also propose to provide for Secretarial review authority for Board and certain ALJ decisions by inserting a new proposed § 160.554 and making conforming changes to 45 CFR 160.548(j) and (k)(1). The same considerations discussed above with respect to DAB review under 45 CFR Part 16 apply to decisions concerning civil money penalties for violations of Administrative Simplification requirements that are subject to the appeal processes set forth under 45 CFR Part 160. Thus, we believe that Secretarial review authority is appropriate under these provisions. Because Board review is not a mandatory part of the appeals process under Part 160 (the Board can decline review of an ALJ decision), we are proposing Secretarial review of both ALJ decisions that the Board has declined to review and Board decisions. To ensure that the Board has the primary review authority, however, we propose that the Secretary will only be able to review an ALJ decision after the Board denies a request for review of the case.

In addition, because of the proposed addition of Secretarial review to the HIPAA Administrative Simplification hearing appeals process, we are proposing to remove the level of review that currently exists at § 160.548(j) for reconsideration by the Board, on request of either party, of its own decisions.

The proposed removal of the reconsideration process would ensure the appeals process remains efficient and is not unduly prolonged. Also, the removal of the reconsideration process would better align the appeals process at Part 160 with the appeals process provided in the regulations at 42 CFR Part 1005, upon which the hearing appeals provisions at 45 CFR Part 160 were originally based.

F. Revision of 45 CFR 1303.17(a) To Conform Timing for Head Start Appeals To Provide for Opportunity for Secretarial Review

The current provisions at 45 CFR 1303.17(a) require that the ''final'' decision be rendered not later than 60 days after the closing of the record before the Board. We propose to revise this regulation by providing that this time limit is applicable only to the timing of the Board's decision, by replacing the phrase ''final decision'' with ''Board's decision.''

G. Revision of 42 CFR Parts 422 and 423 By the addition of 42 CFR §§ 422.1007, 422.1085, 423.1007 and 423.1085 and Revisions to 42 CFR §§ 422.1068, 422.1078(c), 422.1086, 422.1088, 423.1068, 423.1078(c), 423.1086, and 423.1088—Conforming Articulation of Limitations on Review and Provision for Secretarial Review Authority

Recently issued regulations in 42 CFR Parts 422 and 423 do not articulate the principle that administrative law judges and the Board are bound by all applicable statutes and regulations. Articulation of this principle may prevent inappropriate arguments or requests for equitable relief unfounded in law or practice. The articulation of this principle will also make the appeals process more transparent. In addition, we propose to include in the new regulatory provision language parallel to the language proposed for 45 CFR § 16.14 regarding the treatment of published guidance by the Secretary or relevant component. We see no basis to distinguish the scope of review in appeals under 42 CFR Parts 422 and 423 from that proposed in appeals under 45 CFR Part 16. In all cases, the fundamental interpretive authority rests in the Secretary or the component delegated the authority by the Secretary to administer the provisions at issue.

We also propose to provide authority for Secretarial review of Board and ALJ decisions by adding 42 CFR §§ 422.1085 and 423.1085. The same considerations discussed above with respect to Board review under 45 CFR Part 16 apply to decisions concerning initial determinations under Medicare and Medicaid that are subject to the appeal processes set forth under 42 CFR Parts 422 and 423. Thus, we believe that Secretarial review authority is appropriate under these appeal provisions.

Secretarial review ensures that the Department exercises its full authority to interpret and implement statutory and regulatory provisions and ensures that the Secretary's policies are appropriately implemented. The Secretary's views will continue to be ultimately subject to federal court review.

Because DAB review is not a mandatory part of the appeals process under Parts 422 and 423 (the Board can deny review of an ALJ decision), we are proposing Secretarial review of both ALJ decisions and Board decisions. By this, we intend that where the Board denies or dismisses review of an ALJ decision (42 CFR §§ 422.1078 and 423.1078), the Secretary may review the ALJ decision and affirm, reverse or remand, parallel to the authority in the proposed 45 CFR § 16.21. To ensure that the Board has the primary review authority, however, we propose that the time frame for determination of whether the Secretary will review an ALJ decision will run only from the time that the Board denies a request for review of the case.

In sum, we are proposing a similar opportunity for Secretarial review under this provision as we propose under 45 CFR Part 16.

H. Addition of 42 CFR § 498.8 and Revisions to 42 CFR §§ 498.74, 498.89 and 498.90—Conforming Articulation of Limitations on Review and Provision for Secretarial Review Authority

Current regulations in 42 CFR Part 498 do not articulate the principle that administrative law judges and the Board are bound by all applicable statutes and regulations. While in practice, this principle has generally been applied in decisions, and thus articulation of this principle will not result in any change in practice, its articulation may prevent inappropriate arguments or requests for equitable relief unfounded in law or practice. The articulation of this principle will also make the appeals process more transparent. In addition, we propose to include in the new regulatory provision language parallel to the language proposed for 45 CFR § 16.14 regarding the treatment of published guidance by the Secretary or relevant component. We see no basis to distinguish the scope of review in appeals under 42 CFR Part 498 from that proposed in appeals under 45 CFR Part 16. In both cases, the fundamental interpretive authority rests in the Secretary or the component delegated the authority by the Secretary to administer the provisions at issue.

We also propose to provide authority for Secretarial review of Board and ALJ decisions. The same considerations discussed above with respect to Board review under 45 CFR Part 16 apply to decisions concerning initial determinations under Medicare and Medicaid that are subject to the appeal processes set forth under 42 CFR Part 498. Thus, we believe that Secretarial review authority is appropriate under this provision.

In particular, there are a significant number of decisions under Part 498 that may be the first articulation of Departmental interpretation and implementation of policies with respect to applicable statutes and regulations. Only through review of these decisions can the Department exercise its full authority to interpret and implement statutory and regulatory provisions and ensure that the Secretary's policies are appropriately implemented. The Secretary's views will continue to be ultimately subject to federal court review.

Because DAB review is not a mandatory part of the appeals process under Part 498 (the Board can deny review of an ALJ decision), we are proposing Secretarial review of both ALJ decisions and Board decisions. By this, we intend that where the Board denies review of an ALJ decision (42 CFR §§ 498.74(b)(2), 498.83(a)), the Secretary may review the ALJ decision and affirm, reverse or remand, parallel to the authority in the proposed 45 CFR § 16.21. To ensure that the Board has the primary review authority, however, we propose that the time frame for determination of whether the Secretary will review an ALJ decision will run only from the time that the Board denies a request for review of the case.

In sum, we are proposing a similar opportunity for Secretarial review under this provision as we propose under 45 CFR Part 16.

I. Revisions to 42 CFR Part 1005—Conforming Provision for Secretarial Review Authority

We propose to provide regulatory authority for Secretarial review of Board decisions concerning the exclusion, CMP, and assessment authorities

delegated to the I.G. by the Secretary. The same considerations discussed above with respect to Board review under 45 CFR Part 16 and 42 CFR Part 498 apply to such decisions. Thus, we believe that Secretarial review authority is appropriate under this provision.

As with 45 CFR Part 16 and 42 CFR Part 498, there are a significant number of decisions under 42 CFR Part 1005 that may be the first articulation of Departmental interpretation and implementation of policies with respect to applicable statutes and regulations. Only through review of these decisions can the Department exercise its full authority to interpret and implement statutory and regulatory provisions and ensure that the Secretary's policies are appropriately implemented. The Secretary's views will continue to be ultimately subject to federal court review.

The proposed revisions would provide that, when the Board declines review of an ALJ decision under § 1005.21(g), the Secretary may review the ALJ decision, as contemplated in proposed 42 CFR § 1005.24. To ensure that the Board continues to have the primary review authority, we are proposing that the time frame for determination of whether the Secretary will review an ALJ decision will run only from the time that the Board denies a request for review of the case. In addition, the procedure for Secretarial review has been tailored in proposed § 1005.24 to conform to the administrative appeals process in Part 1005.

Because of the limitations on Board review that currently exist in the regulations relating to the exclusion, CMP, and assessment authorities, we do not believe additional clarification is needed with respect to the Board's treatment of published guidance. The regulations limit an ALJ's ability to find invalid or refuse to follow a federal statute or regulation. 42 CFR § 1005.4(c)(1). Also, an ALJ is unable to review the exercise of discretion in imposing a permissive exclusion, CMP, or assessment, or to reduce a period of exclusion to zero. 42 CFR §§ 1005.4(c)(5)–(7). The only issues that may be appealed in an exclusion action are whether the petitioner received proper notice of the exclusion, whether a basis for exclusion exists, and whether the length of the exclusion is unreasonable. 42 CFR § 1001.2007(a). Further, an ALJ is required to follow the determination of the scope and effect of an exclusion. 42 CFR § 1005.4(c)(5). Finally, the Board's standard of review of factual disputes is whether the ALJ's decision is supported by substantial evidence on the whole record. 42 CFR § 1005.21(h). The Board's standard of review of legal disputes is whether the ALJ's decision is erroneous. Id. Because these regulations limit the issues that are appealable, they safeguard the discretion to pursue exclusions, CMPs, or assessments in appropriate cases. The proposed ability of the Secretary to review Board decisions will help preserve the Secretary's authority to interpret the exclusion, CMP, and assessment statutes and regulations.

Therefore, we are not amending the DAB standard of review for matters that fall within 42 CFR Part 1005. We are, however, proposing a Secretarial review process under 42 CFR Part 1005 as is similarly proposed under 45 CFR Part 16.

III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), as amended by Executive Order 13422 (January 2007), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866, as amended, directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule concerns agency administrative appeal procedures, and any direct burden that is imposed on appellants (such as the cost of additional briefing or the cost of delays in the final agency decision) does not reach the economic threshold and, thus, is not considered a major rule. These changes in agency procedures may impact the handling of administrative appeals that involve more than $100 million in a year. But any impact would result from improved application of existing statutes, regulations and Departmental interpretations and must be attributed to those underlying legal requirements. While we conclude that this proposed rule is not economically significant, we nevertheless are characterizing this proposed rule as significant under E.O. 12866 because it will materially affect the procedural rights of grant recipients with respect to appeals. As noted above, the proposed rule would not affect substantive rights to administrative determinations consistent with existing statutes, regulations and Departmental interpretations.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, by virtue of either nonprofit status or having revenues of $6 million to $29 million in any 1 year. Individuals and States are not included in the definition of a small entity. While there are a number of small entities that receive Departmental grants and have access to the DAB for appeal of disallowances, we have determined that the direct effects of the proposed changes in administrative appeal procedures, such as the cost of additional briefing or the cost of delays in the final agency decision, are not economically significant. Thus, we are not preparing an analysis for the RFA because we have determined that this rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Social Security Act, we define a small rural hospital as a hospital that is located outside of a Core-Based Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending

in any one year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $120 million. The direct burden of these changes in administrative appeal procedures, such as the cost of additional briefing or the cost of delays in the final agency decision, does not reach the economic threshold. An indirect impact may result from improved application of existing statutes, regulations and Departmental interpretations, but must be attributed to those underlying legal requirements. As a result, we conclude that this rule will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any significant direct costs on State or local governments, the requirements of E.O. 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 1005

Administrative practice and procedure, Fraud, Grant programs-health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare, Penalties, and Social security.

45 CFR Part 16

Administrative practice and procedure, Grant programs health, and Grant programs-social programs.

45 CFR Part 81

Administrative practice and procedure, and Civil rights.

45 CFR Part 160

Administrative practice and procedure, Computer technology, Health care, Health facilities, Health insurance, Health records, Hospitals, Medicaid, Medicare, Penalties, and Reporting and recordkeeping requirements.

45 CFR Part 1303

Administrative practice and procedure, Education of disadvantaged, Grant programs-social programs, and Reporting and recordkeeping requirements.

For the reasons set forth in this preamble, the Department of Health and Human Services proposes to amend 42 CFR chapters IV (parts 422 and 423 as published on December 5, 2007 (72 FR 68700)) and V and 45 CFR chapters I and XIII as follows:

Title 42—Public Health

PART 422—MEDICARE ADVANTAGE PROGRAM

1. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart T—Appeal procedures for Civil Money Penalties

2. Section 422.1007 is added to read as follows:

§ 422.1007 Limitations of review.

The ALJ and the Departmental Appeals Board may not find invalid or refuse to follow Federal statutes, regulations, or Secretarial delegations of authority and must follow published guidance to the extent not inconsistent with statute or regulation.

3. Section 422.1068 is amended by—

A. Removing the word ''or'' at the end of paragraph (b)(3).

B. Redesignating paragraph (b)(4) as paragraph (b)(5).

C. Adding new paragraph (b)(4).

The addition reads as follows:

§ 422.1068 Administrative Law Judge's decision.

* * * * *

(b) * * *

(4) The Secretary undertakes review of the case pursuant to § 422.1085 of this chapter.

* * * * *

4. Section 422.1078 is amended by revising paragraph (c) to read as follows:

§ 422.1078 Departmental Appeals Board action on request for review.

* * * * *

(c) *Effect of dismissal.* The dismissal of a request for Board review shall be the final agency decision unless the Secretary elects review under § 422.1085.

* * * * *

5. Section 422.1085 is added to read as follows:

§ 422.1085 Secretarial Review of ALJ or Departmental Appeals Board decisions.

The Secretary may review a decision of an ALJ or the Board for error in applying statutes, regulations or interpretive policy.

(a) A copy of each preliminary Board decision will be delivered to the Secretary and the parties within 5 working days from the date the Board issues it. When the Board denies a request for review of an ALJ decision, a copy of the ALJ decision will be delivered to the Secretary and the parties within 5 working days from the date the Board declines to review it.

(b) After delivery of the Board or ALJ decision, the Secretary may, within 30 days of receipt of the decision, undertake review of the case by mailing (or otherwise communicating) to the Board, or the ALJ, and the parties notice of a pending Secretarial review. The underlying decision will be a preliminary decision during the 60-day period after issuance, or a longer period while Secretarial review is pending. If the Secretary decides not to review the case within 30 days, or if the Secretary affirms the decision, summarily, the Board or ALJ decision becomes the final decision of the Secretary on the matter.

(c) After undertaking review of a case, the Secretary may affirm or reverse the underlying decision, or remand the case with instructions for further proceedings. If the Secretary affirms with modifications or reverses the underlying decision, a written decision that sets forth the basis for the action will be the final decision of the Secretary on the matter. If the Secretary remands the case for further proceedings, the original Board or ALJ decision shall be set aside and a written remand order will issue from the Secretary which shall include the reasons for remand and instructions on the proper application of statutes, regulations or interpretive policy. Such

an order will be binding on the Board or ALJ which shall issue a new decision consistent with the Secretary's remand order.

(d) If the Secretary declines review, or disposes of the case by final decision affirming or reversing the Board, the Board shall promptly issue a notice of case closure to the parties.

6. Section 422.1086 is amended by revising the section heading, the introductory text of paragraph (a), and paragraph (c) to read as follows:

§ 422.1086 Effect of the Departmental Appeals Board or Secretarial decision.

(a) *General rule.* A decision of the Board is the final agency decision, unless: the time period permitted for Secretarial review has not elapsed; it is the subject of a Secretarial remand; or it is set aside by a decision by the Secretary to affirm or reverse. If a decision of the Board is set aside by the Secretary, the Secretary shall issue the final agency decision. The final agency decision shall be indicated in the notice of case closure issued by the Board pursuant to 422.1085(d), and shall be binding unless —

* * * * *

(c) *Special rules. Civil money penalty—*

Finality of decision. When CMS imposes a civil money penalty, the final administrative action that initiates the 60-day period for seeking judicial review will be receipt of the notice of case closure issued by the Board pursuant to § 422.1085(d).

7. Section 422.1088 is amended by revising paragraph (a) to read as follows:

§ 422.1088 Extension of time for seeking judicial review.

(a) Any affected party that is dissatisfied with a final administrative decision that imposes a CMP, either a binding decision of the Departmental Appeals Board under 422.1086 or a decision by the Secretary under 422.1085, and is entitled to judicial review must commence a civil action within 60 calendar days from receipt of the notice of case closure issued pursuant to 422.1085(d), unless the Board extends the time in accordance with paragraph (c) of this section.

* * * * *

PART 423—VOLUNTEER MEDICAL PRESCRIPTION DRUG BENEFIT

8. The authority for part 423 continues to read as follows:

Authority: Secs 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

Subpart T—Appeal Procedures for Civil Money Penalties

9. Section 423.1007 is added to read as follows:

§ 423.1007 Limitations of review.

The ALJ and the Departmental Appeals Board may not find invalid or refuse to follow Federal statutes, regulations, or Secretarial delegations of authority and must follow published guidance to the extent not inconsistent with statute or regulation.

10. Section 423.1068 is amended by—

A. Removing the word ''or'' at the end of paragraph (b)(3).

B. Redesignating paragraph (b)(4) as paragraph (b)(5).

C. Adding new paragraph (b)(4).

The addition reads as follows:

§ 423.1068 Administrative Law Judge's decision.

* * * * *

(b) * * *

(4) The Secretary undertakes review of the case pursuant to § 423.1085.

* * * * *

11. Section 423.1078 is amended by revising paragraph (c) to read as follows:

§ 423.1078 Departmental Appeals Board action on request for review.

* * * * *

(c) *Effect of dismissal.* The dismissal of a request for Board review shall be the final agency decision unless the Secretary elects review under § 423.1085.

* * * * *

12. Section 423.1085 is added to read as follows:

§ 423.1085 Secretarial Review of ALJ or Departmental Appeals Board decisions.

The Secretary may review a decision of an ALJ or the Board for error in applying statutes, regulations or interpretive policy.

(a) A copy of each preliminary Board decision will be delivered to the Secretary and the parties within 5 working days from the date the Board issues it. When the Board denies a request for review of an ALJ decision, a copy of the ALJ decision will be delivered to the Secretary and the parties within 5 working days from the date the Board declines to review it.

(b) After delivery of the Board or ALJ decision, the Secretary may, within 30 days of receipt of the decision, undertake review of the case by mailing (or otherwise communicating) to the Board, or the ALJ, and the parties notice of a pending Secretarial review. The underlying decision will be a preliminary decision during the 60-day period after issuance or a longer period while Secretarial review is pending. If the Secretary decides not to review the case within 30 days, or if the Secretary affirms the decision, summarily, the Board or ALJ decision becomes the final decision of the Secretary on the matter.

(c) After undertaking review of a case, the Secretary may affirm or reverse the underlying decision, or remand the case with instructions for further proceedings. If the Secretary affirms with modifications or reverses the underlying decision, a written decision that sets forth the basis for the action will be the final decision of the Secretary on the matter. If the Secretary remands the case for further proceedings, the original Board or ALJ decision shall be set aside and a written remand order will issue from the Secretary which shall include the reasons for remand and instructions on the proper application of statutes, regulations or interpretive policy. Such an order will be binding on the Board or ALJ which shall issue a new decision consistent with the Secretary's remand order.

(d) If the Secretary declines review, or disposes of the case by final decision affirming or reversing the Board, the Board shall promptly issue a notice of case closure to the parties.

13. Section 423.1086 is amended by revising the section heading, the introductory text of paragraph (a), and paragraph (c) to read as follows:

§ 423.1086 Effect of the Departmental Appeals Board or Secretarial decision.

(a) *General rule.* A decision of the Board is the final agency decision, unless: the time period permitted for Secretarial review has not elapsed; it is the subject of a Secretarial remand; or it is set aside by a decision by the Secretary to affirm or reverse. If a decision of the Board is set aside by the Secretary, the Secretary shall issue the final agency decision. The final agency decision shall be indicated in the notice of case closure issued by the Board pursuant to 423.1085(d), and shall be binding unless—

* * * * *

(c) *Special rules. Civil money penalty—*

Finality of decision. When CMS imposes a civil money penalty, the final administrative action that initiates the 60-day period for seeking judicial review will be receipt of the notice of case closure issued by the Board pursuant to 423.1085(d).

14. Section 423.1088 is amended by revising paragraph (a) to read as follows:

§ 423.1088 Extension of time for seeking judicial review.

(a) Any affected party that is dissatisfied with a final administrative decision that imposes a CMP, either a binding decision of the Departmental Appeals Board under § 423.1086 or a decision by the Secretary under § 423.1085, and is entitled to judicial review must commence a civil action within 60 calendar days from receipt of the notice of case closure issued pursuant to § 423.1085(d), unless the Board extends the time in accordance with paragraph (c) of this section.

* * * * *

PART 498— APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFS/MR AND CERTAIN NFS IN THE MEDICAID PROGRAM

15. The authority citation for part 498 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

16. Section 498.8 is added to read as follows:

§ 498.8 Limitations of review.

The ALJ and the Departmental Appeals Board may not find invalid or refuse to follow Federal statutes, regulations, or Secretarial delegations of authority and must follow published guidance to the extent not inconsistent with statute or regulation.

Subpart D—Hearings

17. Section 498.74 is amended by—

A. Redesignating paragraphs (b)(2), (b)(3) and (b)(4) as (b)(3), (b)(4) and (b)(5), respectively.

B. Adding new paragraph (b)(2).

The addition reads as follows:

§ 498.74 Administrative Law Judge's decision.

* * * * *

(b) * * *

(2) The Secretary undertakes review of the case pursuant to § 498.89.

* * * * *

Subpart E—Departmental Appeals Board Review

18. Section 498.83 is amended by revising paragraph (c) to read as follows:

§ 498.83 Departmental Appeals Board action on request for review.

* * * * *

(c) *Effect of dismissal.* The dismissal of a request for Board review shall be the final agency decision unless the Secretary elects review under § 498.89.

* * * * *

19. Section 498.89 is added to read as follows:

§ 498.89 Secretarial Review of ALJ or Departmental Appeals Board decisions.

The Secretary may review a decision of an ALJ or the Board for error in applying statutes, regulations or interpretive policy.

(a) A copy of each preliminary Board decision will be delivered to the Secretary and the parties within 5 working days from the date the Board issues it. When the Board denies or dismisses a request for review of an ALJ decision, a copy of the ALJ decision will be delivered to the Secretary and the parties within 5 working days from the date the Board declines to review it.

(b) After delivery of the Board or ALJ decision, the Secretary may, within 30 days of receipt of the decision, undertake review of the case by mailing (or otherwise communicate) to the Board, or the ALJ, and the parties notice of a pending Secretarial review. The underlying decision will be a preliminary decision during the 60-day period after issuance or a longer period while Secretarial review is pending. If the Secretary decides not to review the case within 30 days, or if the Secretary affirms the decision, summarily, the Board or ALJ decision becomes the final decision of the Secretary on the matter.

(c) After undertaking review of a case, the Secretary may affirm or reverse the underlying decision, or remand the case with instructions for further proceedings. If the Secretary affirms with modifications or reverses the underlying decision, a written decision that sets forth the basis for the action will be the final decision of the Secretary on the matter. If the Secretary remands the case for further proceedings, the original Board or ALJ decision shall be set aside and a written remand order will issue from the Secretary which shall include the reasons for remand and instructions on the proper application of statutes, regulations or interpretive policy. Such an order will be binding on the Board or ALJ which shall issue a new decision consistent with the Secretary's remand order.

(d) If the Secretary declines review, or disposes of the case by final decision affirming or reversing the Board, the Board shall promptly issue a notice of case closure to the parties.

20. Section 498.90 is amended by revising the section heading, the introductory text of paragraph (a), and paragraph (c)(1) to read as follows:

§ 498.90 Effect of the Departmental Appeals Board or Secretarial decision.

(a) *General rule.* A decision of the Board is the final agency decision, unless: The time period permitted for Secretarial review has not elapsed; it is the subject of a Secretarial remand; or it is set aside by a decision by the Secretary to affirm or reverse. If a decision of the Board is set aside by the Secretary, the Secretary shall issue the final agency decision. The final agency decision shall be indicated in the notice of case closure issued by the Board pursuant to § 498.89(d), and shall be binding unless—

* * * * *

(c) *Special rules. Civil money penalty—*

(1) *Finality of decision.* When CMS imposes a civil money penalty, the final administrative action that initiates the 60-day period for seeking judicial review will be receipt of the notice of case closure issued by the Board pursuant to § 498.89(d).

* * * * *

21. Section 498.95 is amended by revising paragraph (a) to read as follows:

§ 498.95 Extension of time for seeking judicial review.

(a) Any affected party that is dissatisfied with a final agency decision and is entitled to judicial review must commence a civil action within 60 days from receipt of the notice of case closure issued by the Board pursuant to § 498.89(d), unless the Board extends the time in accordance with paragraph (c) of this section. The date of receipt is deemed to be 5 days after the date on the notice, unless there is a showing that it was, in fact, received earlier or later.

* * * * *

PART 1005—APPEALS OF EXCLUSIONS, CIVIL MONEY PENALTIES AND ASSESSMENTS

22. The authority citation for part 1005 continues to read as follows:

Authority: 42 U.S.C. 405(a), 405(b), 1302, 1320a–7, 1320a–7a and 1320c–5.

23. Section 1005.20 is amended by revising paragraph (d) to read as follows:

§ 1005.20 Initial decision.

* * * * *

(d) Except for exclusion actions taken in accordance with § 1001.2003 of this chapter and paragraph (e) of this section, unless the initial decision is appealed to the DAB, it will be final and

binding on the parties 30 days after the ALJ serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

* * * * *

24. Section 1005.21 is amended by revising paragraphs (j) and (k) to read as follows:

§ 1005.21 Appeal to DAB.

* * * * *

(j) Except with respect to any penalty, assessment or exclusion remanded to the ALJ or to be reviewed by the Secretary pursuant to § 1005.24 of this chapter, the DAB's decision, including a decision to decline review of the initial decision, becomes final and binding 60 days after the date on which the DAB serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(k)(1) Any petition for judicial review must be filed within 60 days after the decision becomes final and binding as provided in paragraph (j) of this section or § 1005.24(c)(1).

(2) In compliance with 28 U.S.C. 2112(a), a copy of any petition for judicial review filed in any U.S. Court of Appeals challenging a final decision will be sent by certified mail, return receipt requested, to the Chief Counsel to the IG. The petition copy will be time-stamped by the clerk of the court when the original is filed with the court.

(3) If the Chief Counsel to the IG receives two or more petitions within 10 days after the decision becomes final and binding, the Chief Counsel to the IG will notify the U.S. Judicial Panel on Multidistrict Litigation of any petitions that were received within the 10-day period.

25. Section 1005.24 is added to read as follows:

§ 1005.24 Secretarial Review of ALJ or DAB decisions.

The Secretary may review all ALJ decisions that the DAB has declined to review and all DAB decisions for error in applying statutes, regulations or interpretive policy.

(a) A copy of each DAB decision will be delivered to the Secretary within 5 working days from the date the DAB issues it. When the DAB denies a request for review of an ALJ decision, a copy of the ALJ decision will be delivered to the Secretary by the DAB within 5 working days from the date the DAB declines review.

(b) After delivery of a DAB or ALJ decision, the Secretary may undertake a review of the decision.

(1) The Secretary may, within 30 days of receipt of the Board or ALJ decision, undertake review of the decision by mailing (or otherwise transmitting) to the Board, or the ALJ, and the parties notice of a pending Secretarial review. The Secretary's undertaking review of the decision automatically stays the effective date of the decision.

(2) If the Secretary does not undertake a review within 30 days of receipt of the decision, the decision shall be final and binding 60 days after the date the DAB served the parties with the decision, as provided in § 1005.21(j).

(c) Upon review of the decision, the Secretary may affirm or reverse the decision, or remand the matter to the DAB or ALJ for further proceedings.

(1) The Secretary's affirmance or reversal of the decision shall be final and binding on the date the Secretary serves the parties with a written decision setting forth the basis for the decision. Such a decision may incorporate by reference some or all of the reasoning of the reviewed decision, and shall be the final agency action. If service is by mail, the date of service shall be deemed to be 5 days from the date of mailing. Any petition for judicial review must be filed within 60 days after the Secretary serves the parties with the decision.

(2) If the Secretary remands the decision to the DAB or ALJ, the Secretary shall issue a written remand order including the reasons for remand and instructions on the proper application of statutes, regulations or interpretive policy. The Secretary's remand order will be binding on the DAB or ALJ. Upon issuance of the Secretary's remand order, the original DAB or ALJ decision shall be set aside.

(3) Within 60 days of receipt of the Secretary's remand order by the DAB or ALJ, the DAB or ALJ shall serve the parties and the Secretary with a copy of the new decision consistent with the Secretary's remand order. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

Title 45—Public Welfare

PART 16—PROCEDURES OF THE DEPARTMENTAL APPEALS BOARD

1. The authority citation for part 16 continues to read as follows:

Authority: 5 U.S.C. 301 and secs. 1, 5, 6, and 7 of Reorganization Plan No. 1 of 1953, 18 FR 2053, 67 Stat. 631 and authorities cited in the Appendix.

2. The heading of part 16 is revised to read as forth above.

§ 16.2 [Amended]

3. Section 16.2 is amended in paragraph (a) by removing the word ''Grant'' from the phrase ''Departmental Grant Appeals Board.''

4. Section 16.3 is amended by revising paragraph (b) to read as follows:

§ 16.3 When these procedures become available.

* * * * *

(b) The appellant must have received a final written decision, and must appeal that decision within 30 days after receiving it.

* * * * *

5. Section 16.7 is amended by revising paragraph (a) to read as follows:

§ 16.7 The first steps in the appeal process: The notice of appeal and the Board's response.

(a) A prospective appellant must submit a notice of appeal to the Board within 30 days after receiving the final decision. The notice of appeal must include a copy of the final decision, a statement of the amount in dispute in the appeal, and a brief statement of why the decision is wrong.

* * * * *

6. Section 16.12 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 16.12 The expedited process.

* * * * *

(d) *Special expedited procedures where there has already been review.* Some HHS components use a board or other relatively independent reviewing authority to conduct a formal preliminary review process (such as the process described at 42 CFR Part 50, Subpart D) which results in a written decision based on a record including documents or statements presented after reasonable notice and opportunity to present such material. In such cases, the following rules apply to appeals of $25,000 or less instead of those under paragraph (c) of this section.

* * * * *

7. Section 16.14 is revised to read as follows:

§ 16.14 How Board review is limited.

The Departmental Appeals Board may not find invalid or refuse to follow Federal statutes, regulations, or Secretarial delegations of authority and must follow published guidance to the extent not inconsistent with statute or regulation.

8. Section 16.20 is amended by—

A. Revising paragraph (a).

B. Removing paragraphs (d) and (e).

The revision reads as follows:

§ 16.20 How to submit material to the Board.

(a) All submissions should be filed in the manner indicated in the final written decision being appealed or the filing instructions contained in the Appellate Division Practice Manual available on the Board's website at *www.hhs.gov/dab*. The Board's mailing address is set forth on that Web site, and, as of October 1, 2007, is: Department of Health and Human Services, Departmental Appeals Board, Appellate Division, Cohen Building, Rm. G–644, MS 6127, 330 Independence Ave., SW., Washington, DC 20201.

* * * * *

9. Section 16.21 is amended by adding paragraphs (c), (d), and (e) to read as follows:

§ 16.21 Record and decisions.

* * * * *

(c) The Board will promptly notify the Secretary of any disposition of a case on the merits by delivering a copy of each Board decision to the Secretary within 5 working days after the Board issues it.

(d) After delivery of the Board decision, the Secretary may, within 30 days of receipt of the Board decision, undertake review of the case by mailing (or otherwise transmitting) to the Board and the parties notice of a pending Secretarial review. The Board's decision will be a proposed decision during the 30 day period after issuance and while Secretarial review is pending. If the Secretary does not within 30 days determine to review the case, or if the Secretary affirms the Board decision summarily, the Board decision becomes the final decision of the Secretary on the matter, and the Board will promptly so notify the parties.

(e) After undertaking review of a case, the Secretary may affirm or reverse the Board's decision, or remand the case with instructions for further proceedings. In cases involving title IV of the Social Security Act, the Secretary may only affirm or remand the case with instructions for further proceedings. If the Secretary affirms with modifications or reverses the Board's decision, a written decision that sets forth the basis for the action will be the final decision of the Secretary on the matter. If the Secretary remands the case to the Board for further proceedings, the Board's original decision shall be set aside and a written remand order will issue from the Secretary which shall include the reasons for remand and instructions on the proper application of statutes, regulations or interpretive policy. Such an order will be binding on the Board which shall issue a new decision consistent with the Secretary's remand order.

10. Section 16.22 is amended by revising paragraphs (a) and (b)(1) to read as follows:

§ 16.22 The effect of an appeal.

(a) *General*. Until the Board disposes of an appeal and the opportunity for Secretarial review has lapsed, the respondent shall take no action to implement the final decision appealed.

(b) * * *

(1) Suspend funding;

* * * * *

11. Appendix A to Part 16 is amended by—

A. Revising paragraph A.

B. Amending paragraph B by—

i. In paragraph (a)(1), removing the phrase ''Titles I, IV, VI X, XVI(AABD) XIX and XX'' and adding in its place the phrase ''Titles IV, X, XIV, XVI (AABD), XIX, XX and XXI.''

ii. In paragraph (a)(1), removing the phrase ''such as those under sections 403(g) and 1903(g)''.

iii. In paragraph (a)(2), inserting the word ''former'' before the phrase ''Public Health Service.''

iv. In paragraph (a)(3) removing the phrase ''sections 113 and 132'' and adding in its place the phrase ''sections 124 and 143'';

v. Adding paragraph (a)(7).

C. Revising subparagraph (b) of paragraph C.

D. Revosomg paragraph E.

The revisions and addition read as follows:

Appendix A to Part 16—What Disputes the Board Reviews.

A. What this Appendix covers.

This Appendix describes some of the programs which use the procedures in 45 CFR Part 16 for dispute resolution, the types of disputes covered, and any conditions for Board review of final written decisions resulting from those disputes. Disputes under programs not specified in this Appendix may be covered in a program regulation, delegation, memorandum of understanding, or other arrangement between the Board and the head of the appropriate HHS operating component or other agency responsible for administering the program. If in doubt, call the Board. Even though a dispute may be covered here, the Board may still not be able to review it if the limits in paragraph F apply.

B. Mandatory grant programs.

(a) * * *

(7) Disallowance determinations under the Child Care and Development Fund Program as provided in 45 CFR 98.66.

* * * * *

C. Direct, discretionary project programs.

* * * * *

(b) Where an HHS component uses a preliminary appeal process (such as the one described at 42 CFR Part 50, Subpart D), the ''final written decision'' for purposes of Board review is the decision issued as a result of that process.

* * * * *

PART 81—PRACTICE AND PROCEDURE FOR HEARINGS UNDER PART 80 OF THIS TITLE

12. The authority citation for part 81 continues to read as follows:

Authority: 5 U.S.C. 301 and 45 CFR 80.9(d).

Subpart G—Responsibilities and Duties of Presiding Officer

13. Section 81.64 is added to read as follows:

§ 81.64 Scope of review of the presiding officer and the reviewing authority.

The hearing examiner and the reviewing authority may not find invalid or refuse to follow Federal statutes, regulations, or Secretarial delegations of authority and must follow published guidance to the extent not inconsistent with statute or regulation.

PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

14. The authority citation for part 160 continues to read as follows:

Authority: 42 U.S.C. 1302(a), 42 U.S.C. 1320d–1320d8, sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)), and 5 U.S.C. 552.

Subpart E—Procedures for Hearings

15. Section 160.508 is amended by revising paragraph (c)(1) to read as follows:

§ 160.508 Authority of the ALJ.

* * * * *

(c) * * *

(1) May not find invalid or refuse to follow Federal statutes, regulations, or Secretarial delegations of authority and must follow published guidance to the extent not inconsistent with statute or regulation;

* * * * *

16. Section 160.548 is amended by—

A. Redesignating paragraph (h) as paragraph (h)(1).

B. Adding paragraph (h)(2).

C. Revising paragraph (j).

D. Revising paragraph (k)(1).

The revisions and addition read as follows:

§ 160.548 Appeal of the ALJ's decision.

* * * * *

(h) * * *

(2) The Board may not find invalid or refuse to follow Federal statutes, regulations, or Secretarial delegations of

authority and must follow published guidance to the extent not inconsistent with statute or regulation.

* * * * *

(j) Except with respect to a decision remanded to the ALJ, or a decision the Secretary has undertaken to review pursuant to § 160.554 of this part, the Board's decision, including a decision to decline review of the initial decision, becomes final and binding as the decision of the Secretary 60 days after the date on which the Board serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(k)(1) A respondent's petition for judicial review must be filed within 60 days of when the decision of the Secretary becomes final and binding as provided in paragraph (j) of this section or § 160.554(c)(1).

* * * * *

17. Section 160.554 is added to read as follows:

§ 160.554 Secretarial Review of ALJ or Board Decisions.

The Secretary may review all ALJ decisions that the Board has declined to review and all Board decisions for error in applying statutes, regulations or interpretative policy.

(a) A copy of each Board decision will be delivered to the Secretary within 5 working days after the Board issues it. When the Board denies a request for review of an ALJ decision, a copy of the ALJ decision will be delivered to the Secretary by the Board within 5 working days after the Board declines review.

(b) After delivery of a Board or ALJ decision, the Secretary may undertake a review of the decision.

(1) The Secretary may, within 30 days of receipt of the Board or ALJ decision, undertake review of the decision by mailing (or otherwise transmitting) to the Board, or the ALJ, and the parties notice of a pending Secretarial review. The Secretary's undertaking review of the decision automatically stays the effective date of the decision.

(2) If the Secretary does not undertake review within 30 days of receipt of the decision, the decision shall be final and binding as the decision of the Secretary 60 days after the date the Board served the parties with the decision, as provided in § 160.548(j).

(c) Upon review of the decision, the Secretary may affirm or reverse the decision, or remand the matter to the Board or ALJ for further proceedings.

(1) The Secretary's affirmance or reversal of the decision shall be final and binding on the date the Secretary serves the parties with a written decision setting forth the basis for the decision. Such a decision may incorporate by reference some or all of the reasoning of the reviewed decision, and shall be the final agency action. Any petition for judicial review must be filed within 60 days of when the respondent receives notice of the Secretary's decision.

(2) If the Secretary remands the decision to the Board or ALJ, the Secretary shall issue a written remand order including the reasons for remand and instructions on the proper application of statutes, regulations or interpretative policy. The Secretary's remand order will be binding on the Board or ALJ. Upon issuance of the Secretary's remand order, the original Board or ALJ decision shall be set aside.

(3) If service of a ruling or decision issued under this section is by mail, the date of service shall be deemed to be 5 days from the date of the mailing.

PART 1303— APPEAL PROCEDURES FOR HEAD START GRANTEES AND CURRENT OR PROSPECTIVE DELEGATE AGENCIES

18. The authority citation for part 1303 continues to read as follows:

Authority: 42 U.S.C. 9801, *et seq.*

Subpart B—Appeals by Grantees

§ 1303.17 [Amended]

19. Section 1303.17 is amended by removing the phrase ''final decision'' in paragraph (a), in the second sentence, and adding in its place the phrase ''Board's decision''.

Dated: September 17, 2007.

Michael O. Leavitt,

Secretary.

[FR Doc. 07–6221 Filed 12–21–07; 1:00 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket No. FEMA–B–7753]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Proposed rule.

SUMMARY: Comments are requested on the proposed Base (1 percent annual-chance) Flood Elevations (BFEs) and proposed BFE modifications for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the proposed regulatory flood elevations for the reach described by the downstream and upstream locations in the table below. The BFEs and modified BFEs are a part of the floodplain management measures that the community is required either to adopt or show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, these elevations, once finalized, will be used by insurance agents, and others to calculate appropriate flood insurance premium rates for new buildings and the contents in those buildings.

DATES: Comments are to be submitted on or before March 27, 2008.

ADDRESSES: The corresponding preliminary Flood Insurance Rate Map (FIRM) for the proposed BFEs for each community are available for inspection at the community's map repository. The respective addresses are listed in the table below.

You may submit comments, identified by Docket No. FEMA-B–7753, to William R. Blanton, Jr., Chief, Engineering Management Branch, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3151, or (e-mail) *bill.blanton@dhs.gov.*

FOR FURTHER INFORMATION CONTACT: William R. Blanton, Jr., Chief, Engineering Management Branch, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–3151 or.(e-mail) *bill.blanton@dhs.gov.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) proposes to make determinations of BFEs and modified BFEs for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed BFEs and modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations are used to