Medicare Claims Processing Manual
Chapter 33 – Miscellaneous Hold Harmless Provisions

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(Rev. 739, 11-01-05)

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1 - Overview
(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

This chapter addresses miscellaneous Medicare fee-for-service hold harmless provisions that are not addressed elsewhere.

10 - Erroneous Program Guidance: Basis to Waive Penalty
(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

This section addresses Medicare contractor implementation of waiver of penalty when the provider or supplier acted upon erroneous guidance from the Medicare program.

10.1 - Policy
(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

A provider or supplier may be subject to one or more penalties with respect to certain acts or omissions related to the provider or supplier's participation in the Medicare program. However, §903(c) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), which amended §1871(e) of the Social Security Act (the Act), establishes a basis to waive a penalty in certain circumstances. Specifically, §903(c) provides that a provider or supplier shall not be subject to any penalty under an authority of Title XVIII of the Act or under an authority of Title XI of the Act (that relates to Title XVIII) if the basis for imposing the penalty was an act or omission that resulted from the provider or supplier following erroneous guidance from the Medicare program.

The statute provides similarly for waiving interest on an overpayment that was caused by reliance upon erroneous program guidance. However, this section (i.e., §10 and its subsections) applies to the penalty provision only.

10.2 – Basic Conditions That Must Be Met To Waive Penalty
(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

Certain conditions must be met in order to invoke the §903(c) penalty waiver. If all of the relevant conditions are met, then the provider or supplier will not be subject to a penalty for an act or omission that was caused by reliance on such guidance. The following subsections specify the conditions that must be met to invoke the erroneous guidance penalty waiver.

10.2.1 - Guidance Was Erroneous
(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

The first condition that must be met is that the Medicare program guidance must have been erroneous. The analysis of whether the guidance was erroneous must consider two standards and both standards must be met to conclude that the guidance was erroneous for the purpose of invoking the provisions of this section.

The first standard is that the guidance was, in fact, erroneous at the time of the provider or supplier's act or omission that is the basis for the penalty at issue. If there was no error in the guidance then a waiver of the penalty may not be granted.

The second standard is that the error must be material. That is, the error must be the necessary cause of the provider or supplier's act or omission that is the basis for the penalty at issue. If the error is one that would not have caused a reasonable, similarly situated provider or supplier to act or to refrain from acting in the manner that is the basis of the penalty, then the contractor must conclude that a §903(c)-type error is not present and must, therefore, conclude further that a penalty waiver under §903(c) may not be granted.

10.2.2 – Guidance Was Issued by the Secretary or Contractor

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

The second condition that must be met is that the guidance must have been issued by the Secretary or by a Medicare contractor.

Guidance issued by an officer or employee of the Centers for Medicare and Medicaid Services (CMS) is considered to have been issued by the Secretary.

For the purposes of implementing this section, the term "Medicare Contractor" means any Medicare Administrative Contractor (MAC) or an eligible entity with a contract under §1893 of the Act, including but not necessarily limited to a Program Safeguard Contractor.

Guidance issued by any other type of contractor as not qualifying to invoke the penalty waiver unless such guidance is confirmed and communicated by CMS or by a Medicare contractor, as defined above, before the provider or supplier's act or omission that is the basis for the penalty at issue.

10.2.2.1 - Contractor Acted Within Scope of Authority

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

If a Medicare contractor issued the guidance, then the contractor must have been acting within the scope of the contractor's Medicare contract authority.

A Medicare contractor as defined in §10.2.2 shall be presumed to be acting within the scope of its Medicare contract authority (but only for the purpose of implementing this Section) if the guidance:

i) was issued by the contractor in the form of a general communication (e.g., a formally published contractor bulletin, a statement on the contractor's Web site, etc.) or in the form of a communication directed to the particular provider or supplier that seeks to invoke the penalty waiver (or to such provider or supplier's billing agent, attorney, or other agent of such provider or supplier);

ii) addresses a matter that appears to be within the scope of Medicare fee-for-service (e.g., a provider or supplier may not presume that a communication pertaining to the Medicare Advantage Program or to the Medicare Part D drug benefit would also apply to the traditional Medicare fee-for-service program unless there is an express statement to such effect; similarly, a communication that addresses a contractor's private-side health insurance business should not be relied upon for Medicare purposes); and

iii) addresses a matter that appears to be within the scope of responsibility for the type of Medicare contractor that issued the guidance (e.g., home health agencies enrolled in Medicare, which submit claims to a designated A/B MAC (HHH), may not presume that a DME MAC may instruct such agencies in matters related to claim submission (without some further explanation regarding the DME MAC's atypical involvement in home health agency billing matters).

However, if the provider or supplier knew or should have known of any fact that would have caused a reasonable provider or supplier to doubt whether the contractor may have been acting outside the scope of its Medicare contract authority, then the provider or supplier may not rely on the foregoing presumption but, rather, must enquire of the issuing Medicare contractor whether the contractor is authorized to issue the particular guidance. Reconfirmation by the Medicare contractor that it possesses such authority shall be sufficient to satisfy this condition.

See §10.2.8 regarding the related issue as to whether the provider or supplier's reliance on the guidance was reasonable.

10.2.3 - Guidance Was in Writing

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

The third condition that must be met is that the guidance must have been in writing.

The Medicare guidance is considered to be "in writing" if a hardcopy, e-mail, facsimile, floppy disk, or other similar, tangible, reproducible instrument of communicating information is furnished to the provider or supplier. The guidance must possess some form of authentication (e.g., a letterhead) or other indicia that shows that the item was issued by CMS or a Medicare contractor.

Also, a CMS or contractor's Web site posting qualifies as a writing.

The provider or supplier has the burden of documenting the existence of the writing.

10.2.4 - Guidance Related to Item, Service, or Claim

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

The fourth condition that must be met is that the guidance must relate to the furnishing of an item or service or to the submission of a claim for benefits for furnishing such item or service with respect to the provider or supplier submitting such claim.

Guidance related to any item or service furnished or not furnished to a Medicare beneficiary, regardless of whether the item or service is a Medicare-covered item or service, is qualifying to meet the item or service prong of this condition. Guidance related to submitting any filing, including but not necessarily limited to submitting an enrollment form, a claim, a cost report, a Certificate of Medical Necessity (CMN), an Advance Beneficiary Notice (ABN), or additional documentation in support of any filing, is qualifying to meet the claim prong of this condition.

Guidance that is not directly related to the furnishing of an item or service or to the submission of a claim is not within the scope of this Section. Some guidances may require analysis to determine if they relate directly to such matters. For example, a guidance that relates to Health Insurance Portability Accountability Act (HIPAA) compliance, Clinical Laboratory Improvement Act (CLIA) compliance, copyright infringement (of, e.g., CPT coding and descriptors), institutional accreditation and individual licensure, State laws and regulations, Medicaid requirements, or other similar matters for which the legal authority is other than Title XVIII or Title XI of the Act, may not relate directly to the furnishing of an item or service or to the submission of a claim in the context of Medicare fee-for-service and must be analyzed to determine whether the guidance relates directly to such actions in such context.

10.2.5 - Guidance Was Issued Timely

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

The fifth condition that must be met is that the guidance under consideration must have been issued on or after July 24, 2003, and before the act or omission that was the basis for considering the imposition of the penalty.

10.2.6 - Provider Accurately Presented Circumstances in Writing

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

The sixth condition that must be met is that the provider or supplier must have accurately and fully presented the circumstances (relating to the item, service, or claim) in writing to the Medicare contractor or to CMS.

This condition is met if:

a) the presentation of circumstances was made by the provider or supplier or by a billing agent, attorney, or other agent acting on behalf of an expressly identified provider or supplier;

b) the presentation of circumstances was made, directly or indirectly, to the Medicare contractor or to the CMS component that issued the guidance upon which the provider or supplier relied;

c) the presentation of circumstances included all relevant and material facts (**NOTE:** Although the burden is on the provider or supplier to present all relevant and material facts, if the contractor or CMS component that issued the guidance took notice of certain facts in issuing such guidance, then the contractor implementing this section shall also take notice of such facts as if they had been presented by the provider or supplier.);

d) the circumstances were presented accurately, i.e., there was no material ambiguity or misstatement of fact; and

e) the presentation was made in writing (the term "writing" is to be broadly construed as specified in §10.2.3).

10.2.6.1 - Alternative Basis for Satisfying the "Presentation" Condition

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

The "presentation" condition described §10.2.6 shall be deemed to be met if the guidance was communicated generally to all providers and/or suppliers or to a class of providers or suppliers to which the affected provider or supplier belongs rather than having been issued in response to a specific presentation of circumstances by the provider or supplier that is facing the imposition of the penalty.

10.2.7 - Provider Followed Guidance

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

The seventh condition that must be met is that the provider or supplier must have followed the guidance provided by the Medicare contractor or by CMS.

The provider or supplier's act or omission must have been in substantial, but not necessarily complete, accord with the terms of the guidance. Deviation from the guidance, if immaterial, would not necessarily be disqualifying. But even a small deviation from the guidance, if material, could be disqualifying. In general, the greater the specificity of the guidance, the greater must be the provider or supplier's close adherence to such guidance. In addition, the provider or supplier's act or omission in following the guidance must be either the same act or omission that is the basis of the penalty or must be the direct, but not necessarily the immediately proximate cause of such act or omission.

10.2.8 - Provider's Reliance Was Reasonable

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

The eighth condition that must be met is that the provider or supplier's reliance on the guidance provided by the Medicare contractor or by CMS must have been reasonable.

A Medicare program communication (which qualifies as a writing) that was issued to the provider or supplier (specifically, or as part of a class, or to all providers and suppliers generally, that is directly on point with respect to the matter presented by the provider or supplier, and that purports to speak definitively to such matter, creates a rebuttable presumption that the provider or supplier's reliance was reasonable.

However, if the communication, by its own terms, does not purport to be definitive, i.e., it contains relevant and material speculations, disclaimers, a set of possibilities, or other equivocal language, or a request for additional information, such that a reasonable provider or supplier would consider that a further exchange of views or a further presentation of facts, or an additional inquiry was warranted, then no such rebuttable presumption is created.

Also, certain electronically transmitted communications, such as e-mail, although qualifying as a writing, may, in a particular circumstance, be so sparse in content or informal in manner of expression, or may be sent by an individual who is not likely to be authorized to furnish the type of guidance that was issued, that a reasonable provider or supplier would question whether reliance on the guidance, without further inquiry or confirmation, would be reasonable.

Further, the guidance must appear accurate on its face to any reasonable, similarly situated provider or supplier. One circumstance when it would not be reasonable to rely on a particular guidance is when such guidance is in direct conflict with a then current, Medicare program issuance that is applicable in the circumstance addressed by the guidance (unless the guidance itself references such official issuance in terms of supersession or resolving an apparent conflict). Another circumstance when it would not be reasonable to continue to rely on a particular guidance is when the guidance, once accurate (or arguably so), has been superseded by new policy that has been communicated by a program issuance to which the provider or supplier was or should have been privy.

A provider or supplier's reliance on a particular guidance may become questionable or may be determined to be unreasonable if a claim or other filing that was submitted pursuant to such guidance is returned as unprocessable, is denied in whole or in part, is challenged, rejected, or if, in any in other way, a Medicare program communication or other act or omission by CMS or a Medicare contractor would indicate to a reasonable provider or supplier that continued reliance on such guidance would be unreasonable without confirming the continuing validity of the guidance.

If the provider or supplier had received notice of the erroneous nature of the prior guidance, then such provider or supplier shall be bound by the terms of such subsequent notice and may not thereafter rely on the prior, erroneous guidance.

10.3 - Penalty Considered

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

In the context of this section, the term "penalty" is to be broadly construed to include, but not necessarily limited to, a civil money penalty, an assessment, a sanction, a suspension, a termination, or other, similar "penalty".

Examples of matters that are illustrative of a penalty under this section include but are not necessarily limited to: specified remedies under §1819(h)(2)(B),), a sanction under §1833(h)(5)(D), a penalty under §1834(j)(2)(A)(iii), sanctions under §1842(j)(2), §1842(k) or §1842(n)(3), intermediate sanctions under §1846, sanctions under §1848(g)(1)(B), and actions under §1866(b)(2), §1866(d) or §1866(i).

The 10% penalty for filing a "stale" assigned claim, although also illustrative of a penalty under this section, is also subject to the broader conditions for waiver under §1848(g)(4)(B) of the Act. See Pub. 100-04, Medicare Claims Processing Manual, Chapter 1, §70.8.8 et seq.

Although the erroneous-guidance-based penalty waiver of §903(c) applies to all penalties that may be imposed by CMS, this section applies only to those penalties for which implementation has been or may hereafter be delegated to one or more Medicare contractors. Moreover, the foregoing identification of penalties, which are illustrative of §903(c) penalties, does not constitute a delegation to contractors to impose such penalties. Any such delegation would be made in provisions relating to the policies and procedures specific to such penalties or in other program issuances. Accordingly, whether a contractor may grant a penalty waiver in a particular matter will depend, in part, on whether the contractor has been delegated the authority to impose the penalty itself (whether as a standing matter or under a specific, ad hoc delegation on a particular matter or in a particular circumstance).

The term "penalty" is not to be construed so broadly that the application of the penalty waiver would forgive or render moot a Medicare program policy or procedural requirement.

Matters that are not penalties under this section include but are not necessarily limited to the following types of actions: a rejection or a "return-to-provider" action (RTP) on a claim or bill, an initial determination on a claim or bill, a redetermination or reconsideration of such initial determination, a contractor hearing decision regarding such initial determination, a national coverage decision (NCD), a local coverage decision (LCD), a determination made pursuant to a local medical review policy (LMRP), a coding decision, an enrollment decision by a contractor (including the National Supplier Clearinghouse), a notice of program reimbursement (NPR), an overpayment, accrued interest on an unsatisfied overpayment, a CMS Ruling, the Medicare allowed amount or the Medicare payment for a covered item or service, a determination regarding whether a matter is within the scope of this section, or other, similar customary Medicare fee-for-

service program determinations that are not intended to “penalize” a particular provider or supplier for its acts or omissions.

NOTE: Although the foregoing types of actions are not penalties within the scope of this Section, if an erroneous guidance has been issued on such a matter, corrective action may be available under an authority other than this section.

10.4 - General Limitations on Scope

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

The application of §903(c) to waive (or to reverse) the imposition of a penalty has no bearing whatsoever on any other Medicare determination that is adverse to the provider or supplier (such as the denial of a claim in whole or in part). That is, a provider or supplier’s reliance on erroneous guidance has no bearing on an adverse determination on a claim, cost, report, etc., and on the application of Medicare’s rules with respect to the furnishing or non-furnishing of items and services and the submission or non-submission of claims and other filings.

Further, this section does not supersede, nor take precedence over, any other policy or process under any other authority delegated to Medicare contractors to waive, forgive, rescind, or otherwise render inapplicable a penalty when, under such other authority, it is appropriate and administratively more efficient to do so.

Moreover, a penalty waiver determination made under this section does not have precedential effect with respect to any consideration as to whether a provider or supplier was “without fault” under §1870 or §1879 of the Act with respect to the same or related matter.

Finally, this section does not address the application of §903(c) with respect to any penalty for which the authority to impose the penalty has been delegated to the Office of the Inspector General, Department of Health and Human Services (DHHS) or that has been delegated to CMS but not redelegated to one or more Medicare contractors. To the extent that the discussion of penalties in §10.3 may be construed as being in conflict with the foregoing sentence, the instruction contained in the foregoing sentence prevails. However, CMS may elect to delegate a penalty waiver determination to a Medicare contractor on an ad hoc basis regarding a penalty that it has the authority to impose.

10.5 - Notice of Penalty Waiver Policy

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

Notice of the penalty waiver policy shall be included in every notice of the intent to impose a penalty. Such notice must include a statement instructing the provider or supplier how to perfect a penalty waiver request, including the deadline for doing so (which should be congruent with the process for imposing the penalty at issue). In addition, such notice must include either a full statement of the conditions that must be

met for a penalty waiver to be granted or the URL of a Web page where the policies of this section may be reviewed.

In the case of a penalty imposed before the implementation date of this policy, an affected provider or supplier will be afforded the opportunity to request a penalty waiver up to 120 days after such implementation date. As such, an affected provider or supplier has until May 19, 2006, to file a request for a penalty waiver to the appropriate Medicare contractor. Specific notice to an affected provider or supplier of the policies of this section and the extended deadline for filing a waiver request is not required unless the Medicare contractor is actively communicating with such provider or supplier concerning a penalty imposed before the implementation date of this section.

10.6 - Request for a Penalty Waiver Determination

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

A provider or supplier must request a §903(c) penalty waiver determination (but should not file such a request before receiving a notice of an intent to impose a penalty). If the provider elects to request a penalty waiver determination, the provider or supplier must do so by the deadline specified in the notice referenced in §10.5 or, if applicable, by the deadline specified in the second paragraph of §10.5.

Although a penalty waiver determination must customarily be requested by the affected provider or supplier, the contractor having jurisdiction over the matter (see §10.7 below) may initiate such a determination on equitable grounds or for other good cause.

10.7 - Jurisdiction

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

Jurisdiction to make §903(c) penalty waiver determination has two aspects. The first aspect is jurisdiction to determine whether the guidance was erroneous. The second aspect is jurisdiction to complete the penalty waiver determination.

10.7.1 - Jurisdiction Regarding Error

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

The entity that issued the guidance in question has jurisdiction to determine if the guidance was erroneous unless such jurisdiction is delegated to another entity. A contractor that receives a request to make a §903(c) penalty waiver determination with respect to guidance that it did not issue (and for which error jurisdiction has not been delegated) shall refer the request to the issuing entity through its regional office (RO) or project officer unless the contractor retains jurisdiction to complete the penalty waiver determination in accordance with §10.7.2, below. In the latter circumstance, such referral shall be made only to secure a determination regarding whether the guidance was erroneous.

An entity that has jurisdiction to determine error but lacks jurisdiction to complete the determination will make such error determination and then refer that finding to the entity that has jurisdiction to complete the penalty waiver determination.

10.7.2 - Jurisdiction to Complete the Penalty Waiver Determination

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

The entity with the authority to impose the penalty that is the subject of the provider or supplier's request for a §903(c) penalty waiver determination has the jurisdiction to complete such determination (regardless of whether it has jurisdiction to determine if the guidance was erroneous). If the contractor does not possess such authority, then it does not have jurisdiction to complete the §903(c) penalty waiver determination unless a specific delegation of authority is issued to the contractor by the contractor's project officer or other competent CMS authority, which authorizes the contractor to complete such determination. Absent such delegation, the contractor must refer the provider or supplier's request to the entity that possesses such authority.

See §10.3 regarding whether a matter is properly considered a §903(c) penalty under this section. See also §10.4 regarding whether the matter has been delegated to the contractor. If the matter raised by the provider or supplier is outside the scope of matters discussed in the foregoing specified subsections, then the contractor to which a §903(c) request has been made will decline jurisdiction absent a specific grant of jurisdiction on such matter and will refer the matter to the contractor's RO or project officer, as appropriate.

10.8 - Determining Whether the Guidance Was Erroneous

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

Consideration as to whether the guidance at issue was erroneous is based on the standards specified in §10.2.1.

If the guidance is determined to have been not erroneous under those standards, and if the contractor also has jurisdiction to complete the penalty waiver determination, then no further determinations will be made regarding the conditions specified in §10.2 but, rather, notice will be given to the provider or supplier of an adverse penalty waiver determination and the case will be closed.

If the guidance is determined to have been not erroneous, but the contractor does not also have jurisdiction to complete the penalty waiver determination, the case will be referred to the entity that has such jurisdiction (through the RO or project officer if necessary or appropriate) with the information the guidance was not erroneous.

If the guidance is determined to have been erroneous and if the contractor also has jurisdiction to complete the penalty waiver determination, then the contractor shall complete such determination in accordance with the procedures specified in §10.9.

If the guidance is determined to have been erroneous but the contractor does not have jurisdiction to complete the penalty waiver determination, then the contractor shall advise the entity having such jurisdiction (through the RO or project officer if necessary or appropriate) that the guidance was erroneous, furnishing such additional information as will facilitate the completion of the penalty waiver determination.

10.9 - Completing the Penalty Waiver Determination

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

The process of completing the penalty waiver determination includes consideration of four threshold matters, i.e., the timeliness of the request, ripeness, the sufficiency of information furnished by the provider or supplier, and mootness. If adjudication of the matter is not barred by any of the foregoing matters, then the remaining required conditions specified in §§10.2.2 through 10.2.8 are considered.

10.9.1 - Timeliness of Request

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

The contractor shall decline to make a penalty waiver determination on a particular matter if the provider or supplier did not timely request such a determination in accordance with § 10.6. However, even if the provider or supplier did not timely request such determination, the contractor should, nevertheless, make a penalty waiver determination on equitable grounds or for other good cause.

10.9.2 - Ripeness

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

The contractor shall decline to make a penalty waiver determination on a particular matter if the contractor has not given notice to the requesting provider or supplier of the intent to impose a penalty or has rescinded such notice pending further consideration of the matter.

However, a contractor should make a penalty waiver determination even if the contractor has not given notice to the provider or supplier of the intent to impose a penalty or even if the provider or supplier has not requested a penalty waiver determination, provided the contractor determines that making such determination will likely promote administrative efficiency in the particular circumstance or for other good cause.

10.9.3 - Sufficient Information

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

The provider or supplier has the burden of proof and of production of evidence to show that a §903(c) penalty waiver should be granted in the particular circumstance. However, the contractor should take notice of any relevant and material fact that is not subject to reasonable dispute.

The contractor shall make a preliminary evaluation regarding whether the provider or supplier has submitted sufficient information to permit the contractor to determine whether all of the remaining seven conditions specified in §10.2 have been met. If the provider or supplier's request does not furnish sufficient information to make a determination on each such condition, the contractor shall advise the provider or supplier of all deficiencies and allow 45 days for the information to be supplied. If sufficient information is not supplied within the allotted period, the contractor shall close the penalty waiver case and proceed with its normal process for considering whether the penalty should be imposed. However, the contractor may at its sole discretion, grant an extension of time to supply information.

10.9.4 - Mootness

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

If, at any stage of the penalty waiver determination process, the contractor intending to impose the penalty determines that the penalty will not be imposed on a basis other than §903(c), the contractor shall consider the penalty waiver issue to be moot and shall close the case.

10.9.5 - Required Conditions Other Than Error

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

If the guidance has been determined to be erroneous, and if adjudication of the matter is not barred by issues of the timeliness of the request, of ripeness, of sufficiency of information, or of mootness, then the contractor shall complete a penalty waiver determination by making separate determinations on each of the remaining required conditions specified in §§10.2.2 through 10.2.8. The contractor shall make findings on each such condition, notwithstanding that a particular condition was not met.

10.9.6 - Completing the Determination

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

The contractor shall complete the §903(c) determination within either: a) 60 days of a provider or supplier's direct request for such a determination if the contractor has jurisdiction to determine both error and all other conditions or b) 45 days of receiving an error-only determination from another entity.

However, delays caused by a provider or supplier's failure to furnish sufficient information, by the failure of another contractor or CMS component to make a proper and timely referral of a matter, or by the failure of CMS to timely clarify proper jurisdiction in a particular matter, are not included within this timeframe.

If the contractor cannot complete the determination within the applicable deadline, then the contractor shall furnish notice of such delay to the provider or supplier, shall take no action to impose the penalty at issue, and shall seek to resolve the issues causing the delay.

If the contractor determines that all of the conditions specified in §10.2 have been met, then the contractor shall approve the provider or supplier's request for a penalty waiver and shall not impose, or shall rescind, the penalty at issue.

If the contractor determines that any condition among those specified in §10.2 has not been met, then the contractor shall deny the provider or supplier's request for a penalty waiver and shall thereafter consider the penalty at issue solely under the terms of the authority for imposing such penalty or under such other authority as may be applicable in the circumstance.

10.10 - Notice of the Penalty Waiver Determination

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

The contractor shall furnish notice to the provider or supplier of the contractor's penalty waiver determination.

If the penalty waiver was not granted in whole or in part, the notice must specify the basis for the adverse determination. Every notice of a penalty waiver determination must include statements: a) that the provider or supplier has a right to a reconsideration of the penalty waiver determination, b) describing the means for filing a request for reconsideration, c) specifying the deadline for making such a request, and d) that the provider may also request a hearing and may present written evidence and arguments.

The contractor should elect to furnish notice concerning the penalty waiver determination coincident with, or in lieu of, its determination regarding the imposition of the penalty under the penalty authority.

10.11 - Reconsideration of the Penalty Waiver Determination

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

A provider or supplier may request a reconsideration of an adverse penalty waiver determination.

The provider or supplier must file such request for reconsideration in accordance with the procedures and deadline specified in the notice of the adverse determination described in §10.10 above.

If a request for reconsideration is timely filed by the provider or supplier, the contractor shall reconsider its penalty waiver determination and shall allow the provider or supplier to be heard concerning the basis of the provider or supplier's request or to submit written arguments and evidence in support of its contentions, provided such written arguments and evidence are submitted within 30 days of the provider or supplier's request for reconsideration or within 10 days of any hearing that may be requested on the matter, whichever is later.

The contractor shall complete its reconsideration within 30 days of receiving such request, of any hearing that may be conducted on the matter, or of any filing of written arguments or evidence, whichever is later.

The contractor shall make a reconsideration decision based on the standards specified in this section and furnish appropriate notice of such decision to the provider or supplier.

10.12 - Recordkeeping

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

The contractor must compile a record of each penalty waiver determination.

Such record must include all documentary material that relates to a particular matter, regardless of form or format.

Such record shall be associated with the record concerning the penalty in question and shall be retained and disposed of in accordance with the record retention policies and procedures that apply to the maintenance of the associated penalty record.

In the case of a request for which no certain penalty attaches, such as in the case of a transfer, the penalty waiver record shall be retained and disposed of in accordance with the record retention policies and procedures that apply to claims records generally.

10.13 - Reporting

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

Contractors shall submit both detailed and summary quarterly reports of penalty activities and shall attach to such reports documentation of all previously unreported erroneous guidances.

10.14 - Corrective Action

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

Upon a determination that a particular guidance is erroneous, if corrective action with respect to such guidance has not previously been taken, the contractor shall take appropriate action to eliminate or mitigate the effects of the erroneous guidance.

10.15 - Effective Date

(Rev. 739, Issued: 11-01-05, Effective: 07-24-03, Implementation: 01-19-06)

This section applies to guidance issued on or after July 24, 2003 (that relates to Medicare fee-for-service).

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R739CP	11/01/2005	Initial Publication of Chapter-Erroneous Guidance-Basis to Waive Penalty	01/19/2006	3898

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