

CMS Manual System

Pub 100-04 Medicare Claims Processing

Transmittal 739

Department of Health &
Human Services (DHHS)

Centers for Medicare &
Medicaid Services (CMS)

Date: NOVEMBER 1, 2005

Change Request 3898

SUBJECT: Erroneous Guidance - Basis to Waive Penalty

I. SUMMARY OF CHANGES: This Section addresses Medicare contractor implementation of waiver of penalty when the provider or supplier acted upon erroneous guidance from the Medicare program.

NEW/REVISED MATERIAL

EFFECTIVE DATE: July 24, 2003

IMPLEMENTATION DATE: January 19, 2006

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R = REVISED, N = NEW, D = DELETED – *Only One Per Row.*

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N	33/Table of Contents
N	33/1/Overview
N	33/10/Erroneous Program Guidance: Basis to Waive Penalty
N	33/10.1/Policy
N	33/10.2/Basic Conditions That Must Be Met To Waive Penalty
N	33/10.2.1/Guidance Was Erroneous
N	33/10.2.2/Guidance Was Issued by the Secretary or Contractor
N	33/10.2.2.1/Contractor Acted Within Scope of Authority
N	33/10.2.2.3/Guidance Was in Writing

N	33/10.2.5/Guidance Was Issued Timely
N	33/10.2.6/Provider Accurately Presented Circumstances in Writing
N	33/10.2.6.1/Alternative Basis for Satisfying the “Presentation” Condition
N	33/10.2.7/Provider Followed Guidance
N	33/10.2.8/Provider’s Reliance Was Reasonable
N	33/10.3/Penalty Considered
N	33/10.4/General Limitations on Scope
N	33/10.5/Notice of Penalty Waiver Policy
N	33/10.6/Request for a Penalty Waiver Determination
N	33/10.7/Jurisdiction
N	33/10.7.1/Jurisdiction Regarding Error
N	33/10.7.2/Jurisdiction to Complete the Penalty Waiver Determination
N	33/10.8/Determining Whether the Guidance Was Erroneous
N	33/10.9/Completing the Penalty Waiver Determination
N	33/10.9.1/Timeliness of Request
N	33/10.9.2/Ripeness
N	33/10.9.3/Sufficient Information
N	33/10.9.4/Mootness
N	33/10.9.5/Required Conditions Other Than Error
N	33/10.9.6/Completing the Determination
N	33/10.10/Notice of the Penalty Waiver Determination
N	33/10.11/Reconsideration of the Penalty Waiver Determination
N	33/10.12/Recordkeeping
N	33/10.13/Reporting
N	33/10.14/Corrective Action

III. FUNDING:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2006 operating budgets.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

Pub. 100-04	Transmittal: 739	Date: November 1, 2005	Change Request 3898
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SUBJECT: Erroneous Guidance – Basis to Waive Penalty

I. GENERAL INFORMATION

A. Background: 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 for waiving the penalty in certain circumstances. Specifically, §903(c) establishes that, subject to certain conditions, 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 the penalty that would have otherwise been applicable was that the provider or supplier acted in accordance with erroneous guidance from the Medicare program.

This statutory amendment also provides for waiving interest if the overpayment that is the basis for assessing such interest resulted from the provider or supplier acting in accordance with erroneous guidance from the Medicare program. However, this transmittal addresses the penalty provision only.

B. Policy: A provider or supplier shall not be subject to a penalty under any authority specified in Title XVIII or in Title XI (that relates to Title XVIII) with respect to an act or omission that resulted from the provider or supplier having followed erroneous written Medicare program guidance with respect to furnishing items or services or with respect to the submission of a claim or other filing.

II. BUSINESS REQUIREMENTS

“Shall” denotes a mandatory requirement

“Should” denotes an optional requirement

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3898.1	The contractor shall not impose a penalty under any authority specified in Title XVIII or in Title XI (that relates to Title XVIII) with respect to an act or omission that resulted from the provider or supplier having followed erroneous written Medicare program guidance with	X	X	X	X					PSCs, MIP contractors under §1893 of the Act

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
	respect to furnishing items or services or with respect to the submission of a claim or other filing.									
3898.2	<p>The contractor shall implement Requirement 3898.1 only if all of the following conditions are met:</p> <ol style="list-style-type: none"> 1. The guidance was erroneous. 2. The guidance was issued by the Secretary or was issued by a Medicare contractor acting within the scope of the contractor’s Medicare contract authority. 3. The guidance was in writing. 4. The guidance related 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. 5. The guidance was issued timely. 6. The provider or supplier accurately and fully presented the circumstances relating to such items, services, and claim to the Medicare contractor or to the Centers for Medicare and Medicaid Services (CMS) and did so in writing. 7. The provider or supplier followed the guidance provided by the Medicare contractor (or by CMS). 8. The provider or supplier’s reliance on such guidance was reasonable. 	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.3	The contractor shall apply the standards specified in Requirements 3898.3.1 through 3898.3.8.5 to determine whether the conditions specified in Requirement 3898.2 are met.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.3.1	<p>The contractor, with respect to determining whether the guidance was erroneous, shall consider the condition to be met if both of the following standards are met:</p> <ol style="list-style-type: none"> a) The guidance was, in fact, erroneous at the 	X	X	X	X					PSCs, MIP contractors under §1893 of the Act

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
	<p>time of the provider or supplier’s act or omission that is the basis for the penalty at issue. (If the guidance contains no error, then a penalty waiver may not be granted); and</p> <p>b) If the guidance contained an error, then such error must be material. (That is, the error must have been 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 refrain from acting in the manner that is the basis for the penalty, then the contractor must conclude that a §903(c)-type error is not present.)</p>									
3898.3.2	<p>The contractor, with respect to determining whether the guidance was properly issued, shall consider that the condition is met if the each of the applicable following standards is met.</p> <p>a) The guidance is considered to have been issued by the Secretary if it was issued by an officer or employee of the CMS.</p> <p>b) The guidance is considered to have been issued by a Medicare contractor if it was issued by a Fiscal Intermediary, Regional Home Health Intermediary, Carrier, Durable Medical Equipment Regional Carrier, or an eligible entity with a contract under §1893 of the Act, including but not necessarily limited to Program Safeguard Contractors.</p> <p>c) Guidance issued by any other type of contractor is not qualifying unless such guidance is confirmed by an officer or employee of CMS or by a Medicare contractor as specified in paragraph (b) above, before the provider or supplier’s</p>	X	X	X	X					PSCs, MIP contractors under §1893 of the Act

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
	<p>act or omission that is the basis for the penalty at issue.</p> <p>d) A Medicare contractor, as specified in paragraph (b) above, shall be presumed to be acting within the scope of its Medicare contract authority (but only for the purpose of considering whether Requirement 3898.1 shall be applied) if the guidance:</p> <p>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 erroneous guidance exception (or to such provider or supplier’s billing agent, attorney, or other agent of such provider or supplier);</p> <p>ii. is, on its face, on a matter that appears to be within the scope of Medicare fee-for-service; and</p> <p>iii. is, on its face, on a matter that appears to be within the scope of responsibility for the type of contractor that issued the guidance.</p>									
3898.3.3	The contractor, with respect to determining whether the guidance was in writing, shall consider as a writing: a hardcopy, e-mail, facsimile, floppy disk, or other similar, tangible or reproducible instrument of communicating information that is furnished or made available to the provider or supplier. A Web site posting also qualifies as a writing.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3898.3.4	The contractor, with respect to determining whether the guidance related to the furnishing of an item or service or to the submission of a claim, shall broadly construe the terms “item”, “service”, and “claim” and shall, with respect to the term “claim”, consider as qualifying any filing, including but not necessarily limited to an enrollment form, a claim, a bill, a cost report, a Certificate of Medical Necessity , an Advance Beneficiary Notice , or any documentation in support of a filing.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.3.4.1	The contractor, with respect to determining whether the guidance related to the furnishing of an item or service or to the submission of a claim, shall not construe the terms “item”, “service”, and “claim” so broadly as to include matters not directly relating to the furnishing of an item or service or to the submission of a claim. A guidance that relates to HIPAA compliance, Clinical Laboratory Improvement Act compliance, copyright infringement (of, e.g., CPT coding and descriptors), institutional accreditation and individual licensure, State laws and regulations, and Medicaid requirements, and other similar matters for which the legal authority is other than Titles XVIII and XI of the Social Security Act (SSA), must be analyzed to determine whether the guidance relates <u>directly</u> to the furnishing of an item or service or to the submission of a claim in the context of Medicare fee-for-service.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.3.5	The contractor, with respect to determining whether the guidance was timely issued, shall consider that the condition is met if the guidance was issued on or after July 24, 2003 and before the act or omission that is the basis for imposing the penalty.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3898.3.6	<p>The contractor, with respect to determining whether the provider presented the circumstances accurately and in writing, shall consider whether the condition is met in accordance with the following standards:</p> <p>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;</p> <p>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;</p> <p>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 the guidance, then the contractor implementing this Transmittal shall also take notice of such facts as if they had been presented by the provider or supplier.);</p> <p>d) the circumstances were presented accurately, i.e., there was no material ambiguity or misstatement of fact; and</p> <p>e) the presentation was made in writing (and the term “writing” is to be broadly construed as specified in Requirement 3898.3.3).</p>	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.3.6.1	<p>This standard shall be deemed satisfied and the condition described in Requirement 3898.2, paragraph 2 shall be deemed to be met if the guidance in question was communicated to all providers or suppliers generally or to a class of providers or suppliers to which the affected provider or supplier belongs.</p>	X	X	X	X					PSCs, MIP contractors under §1893 of the Act

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3898.3.7	The contractor, with respect to determining whether the provider or supplier followed the guidance provided by the Medicare contractor or by CMS, shall consider the condition to be met if the provider or supplier’s act or omission was in substantial, even if not necessarily complete, accord with the terms of the guidance.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.3.7.1	The contractor shall consider that a provider or supplier’s 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.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.3.7.2	The contractor shall consider that the provider or supplier’s act or omission in following the guidance must have been either the same act or omission that is the basis for imposing the penalty or the direct but not necessarily the immediately proximate cause of the act or omission that is the basis for imposing the penalty.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.3.8	The contractor, with respect to determining whether provider or supplier’s reliance on such guidance was reasonable, shall apply the guidelines specified in Requirements 3898.3.8.1 through 3898.3.8.5.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.3.8.1	The contractor shall consider that a writing from a Medicare contractor or CMS component that is directly on point on the matter presented by the provider or supplier creates a rebuttable presumption that the provider or supplier’s reliance was reasonable. However, if the writing, by its own terms, does not purport to be definitive, i.e., it contains relevant and material	X	X	X	X					PSCs, MIP contractors under §1893 of the Act

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
	speculations, disclaimers, statement of possibilities, or other equivocal language, or contains a request for clarification or 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.									
3898.3.8.2	The contractor shall consider that 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 authorized to furnish the type of guidance that was issued, that in a particular circumstance, a reasonable provider or supplier would question whether reliance on the particular guidance, without further inquiry or confirmation, would be reasonable.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.3.8.3	The contractor shall consider that guidance must appear accurate on its face to any reasonable, similarly situated provider or supplier. For example, one circumstance when it would not be reasonable to rely on a particular guidance is when the guidance is in direct conflict with a then current, official 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	X	X	X	X					PSCs, MIP contractors under §1893 of the Act

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
	have been privy.									
3898.3.8.4	The contractor shall consider that a provider or supplier’s continuing 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 rejected or 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.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.3.8.5	The contractor shall consider that if the provider or supplier received notice of the erroneous nature of a 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.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.4	The contractor shall apply the specifications in Requirements 3898.4.1 through 3898.4.6.1 regarding what matters are within the scope of this transmittal.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.4.1	The contractor shall, in the context of this transmittal, construe broadly the term “penalty” to include, but not necessarily be limited to, a civil money penalty, an assessment, a sanction, a suspension, a termination, or other, similar “penalty”.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3898.4.2	The contractor should consider that 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), actions under §1866(b)(2), §1866(d), or §1866(i), or other, similar “penalties” are illustrative of a penalty within the scope of this transmittal, provided Requirement 3898.4.4 is met.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.4.3	The contractor shall consider that, although the 10% penalty for filing a “stale” assigned claim under §1848(g)(4)(B) of the Act is also illustrative of a “penalty” under this section, it is also subject to the broader conditions for waiver as specified in Pub. 100-04, Medicare Claims Processing Manual, Chapter 1, §70.8.8 et seq.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.4.4	The contractor shall, notwithstanding the specifications of Requirements 3898.4.1, 3898.4.2, and 3898.4.3, apply the term “penalty” in the context of this transmittal only to those penalties the imposition of which has been expressly delegated to the Medicare contractor (as defined in Requirement 3898.3.2, paragraph (b)) or that may hereafter be expressly delegated to such contractor.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.4.4.1	An express delegation of authority may be in the form of a Joint Signature Memorandum (JSM), a transmittal issued by the Office of Strategic Operations and Regulatory Affairs, a provision in a Statement of Work, any program issuance delegating such authority which preceded the Medicare Change Management process, or any other form of delegation that is or may be approved by the Director, Medicare Contractor Management Group.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3898.4.5	The contractor shall not construe the term “penalty” so broadly as to forgive or render moot a Medicare program requirement.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.4.6	The contractor shall not construe the term “penalty” so broadly as to include the following types of actions: a rejection or a “return-to-provider” action 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, a local coverage decision, a determination made pursuant to a local medical review policy, a coding decision, an enrollment decision by a contractor (including the National Supplier Clearinghouse), a notice of program reimbursement, 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 transmittal, 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.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.4.6.1	The contractor shall not construe the specification of actions in Requirement 3898.4.6, which are not penalties within the scope of this transmittal, to suggest that corrective action should not be taken when erroneous guidance has been issued on such matters. Requirement 3898.4.6 shall be understood to mean solely that any such corrective action as may be necessary or appropriate shall not be undertaken pursuant to	X	X	X	X					PSCs, MIP contractors under §1893 of the Act

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
	the penalty waiver policy of this transmittal but, rather, shall be implemented via whatever administrative discretion has already been delegated to the contractor for the matter in question.									
3898.4.7	The contractor, when considering whether a provider or supplier was “without fault” under §1870 or §1879 of the Act, shall not consider as precedential for such consideration any prior or contemporaneous penalty waiver determination made on the same or related matter, whether such penalty waiver determination was made by the contractor or by another contractor authorized to make such penalty waiver determination.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.5	The contractor shall not apply the terms of this transmittal to any Medicare determination other than a penalty, including but not necessarily limited to the actions specified in Requirement 3898.4.6.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.5.1	The contractor shall not apply the terms of this transmittal to supersede the policies and procedures of any other authority available to Medicare contractors to waive, forgive, rescind, cancel, or otherwise render inapplicable a penalty when, under such other authority, it is appropriate and administratively more efficient to do so.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.5.2	The contractor shall not construe a penalty waiver request as a challenge to or as an appeal of the underlying penalty nor as a basis to deny appeal rights that would otherwise apply to such penalty.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.5.3	The contractor shall not construe an administrative appeal of a penalty as a basis to not consider penalty waiver if such a waiver might otherwise be applicable.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3898.5.3.1	If it appears that a §903(c)-type error may apply to the penalty at issue, the contractor shall either assist the provider or supplier in perfecting a penalty waiver request or, if circumstances permit, invoke Requirement 3898.9.2.1 to make a penalty waiver determination on its own initiative.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.5.4	The contractor shall not apply the terms of this transmittal with respect to any penalty for which the authority to impose such penalty has been delegated to the Office of the Inspector General, Department of Health and Human Services, that has been delegated to CMS but not re-delegated by CMS to the contractor, or that has been delegated to any other entity.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.5.5	The contractor shall consider that, to the extent that the discussion of penalties in Requirement 3898.4.1 through Requirement 3898 4.6.1 may be construed as being in conflict with Requirement 3898.5.4, the instruction specified in Requirement 3898.5.4 prevails.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.6	The contractor shall include notice of the policy established by this transmittal in every notice of its intent to impose a penalty or in every notice of its imposition of a penalty (if such notice-of-intent is not employed by the contractor with respect to the particular type of penalty).	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.6.1	The contractor shall include in such notice a statement instructing the provider or supplier as to how it can perfect a request for a penalty waiver, including the deadline for doing so (which deadline should, if feasible, be congruent with the process for considering the penalty at issue).	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.6.1.1	The contractor shall, in the case of a penalty imposed before the implementation date of this transmittal, afford an affected provider or supplier the opportunity to request a penalty	X	X	X	X					PSCs, MIP contractors under §1893 of the Act

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
	waiver up to 120 days after such implementation date.									
3898.6.1.2	The contractor shall, if it is actively communicating with a provider or supplier concerning a penalty imposed before the implementation date of this transmittal, furnish specific notice to such provider or supplier concerning the policy specified by this transmittal and of the extended timeframe for filing a waiver request. The contractor should also furnish such specific notice to similarly affected providers and suppliers with which the contractor is not actively communicating regarding a penalty; however, such specific notice is not required.	X	X	X	X				PSCs, MIP contractors under §1893 of the Act	
3898.6.2	The contractor shall also include in such notice a statement instructing the provider or supplier of the conditions that must be met to secure a waiver of the penalty under §903(c) or a reference to a Web site where the policies of this transmittal may be reviewed.	X	X	X	X				PSCs, MIP contractors under §1893 of the Act	
3898.6.3	The contractor shall take appropriate precautions to ensure that such notice clearly distinguishes between the steps the provider or supplier must take to administratively appeal the penalty versus the steps that are necessary to request a penalty waiver under the policy established by this transmittal. Moreover, the contractor shall also make clear that the provider or supplier may elect to pursue both an administrative appeal of the penalty and request a penalty waiver under the terms of this transmittal.	X	X	X	X				PSCs, MIP contractors under §1893 of the Act	

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3898.7	Upon receipt of a request for a §903(c) penalty waiver determination, the contractor shall first determine whether and to what extent it has jurisdiction to make such a determination. The contractor shall consider two aspects of jurisdiction when doing so, as specified in Requirements 3898.7.1 and 3898.7.2.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.7.1	The contractor shall consider the question of jurisdiction to determine whether the guidance was erroneous. The contractor shall assume jurisdiction to determine whether the guidance was erroneous if: a) the contractor issued the guidance in question; or b) a general or specific delegation of authority for such purpose is issued to the contractor by the contractor’s project officer or other competent CMS authority.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.7.1.1	The contractor that lacks jurisdiction to determine whether the guidance was erroneous shall refer the request for a §903(c) penalty waiver determination to the entity (i.e., other contractor or CMS component) that issued the guidance or, if such entity is unknown, to the Regional Office (RO) or project officer, as appropriate.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.7.1.2	The contractor possessing jurisdiction to determine whether the guidance was erroneous shall make such determination in accordance the procedures specified in Requirement 3898.8.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.7.2	The contractor shall consider the question of jurisdiction to complete the §903(c) penalty waiver determination. The contractor shall assume such jurisdiction to complete the §903(c) penalty waiver determination if: a) the contractor has the authority to impose the penalty that is the subject of the request for a	X	X	X	X					PSCs, MIP contractors under §1893 of the Act

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
	penalty waiver determination; or b) a general or specific delegation of authority for such purpose is issued to the contractor by the contractor’s project officer or other competent CMS authority.									
3898.7.2.1	The contractor lacking jurisdiction to complete the penalty waiver determination shall refer the penalty waiver request to the entity that possesses such authority or, if such entity is unknown, to the RO or the contractor’s project officer, as appropriate.	X	X	X	X				PSCs, MIP contractors under §1893 of the Act	
3898.7.2.2	The contractor having jurisdiction to complete the penalty waiver determination shall make such determination in accordance with Requirement 3898.9.	X	X	X	X				PSCs, MIP contractors under §1893 of the Act	
3898.8	The contractor shall determine whether the guidance at issue was erroneous based on the standards specified in Requirement 3898.3.1.	X	X	X	X				PSCs, MIP contractors under §1893 of the Act	
3898.8.1	If the guidance is determined to have been not erroneous and if the contractor has jurisdiction to complete the penalty waiver determination, then the contractor shall make no further determinations regarding the conditions specified in Requirement 3898.2 but, rather, shall give notice to the provider or supplier of the adverse penalty waiver determination and then close the case.	X	X	X	X				PSCs, MIP contractors under §1893 of the Act	
3898.8.2	If the guidance is determined to have been not erroneous, but the contractor does not have jurisdiction to complete the penalty waiver determination, the contractor shall advise the entity that has such jurisdiction (through the RO or project officer if necessary or appropriate) that the guidance was found to have been not erroneous.	X	X	X	X				PSCs, MIP contractors under §1893 of the Act	

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3898.8.3	If the guidance is determined to have been erroneous and if the contractor has jurisdiction to complete the penalty waiver determination, then the contractor shall complete such determination in accordance with the procedures specified in Requirement 3898.9.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.8.4	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.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.9	The contractor shall, if the guidance is determined to have been erroneous in accordance with the applicable procedure specified in Requirement 3898.8.1 through Requirement 3898.8.4, complete a §903(c) penalty waiver determination in accordance with the procedures specified in Requirements 3898.9.1 through 3898.9.6.4.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.9.1	The contractor shall decline to complete a penalty waiver determination on a particular matter if the provider or supplier did not timely request such determination in accordance with the process noticed to the provider or supplier as specified in Requirement 3898.6.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.9.1.1	Notwithstanding the provider or supplier’s failure to timely request such determination, the contractor should complete a penalty waiver determination on equitable grounds or for other good cause.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3898.9.2	Except as specified in Requirement 3898.9.2.1, the contractor shall decline to complete a penalty waiver determination on a particular matter if the contractor (or other entity) 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.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.9.2.1	The contractor should make a penalty waiver determination even if notice has not been given 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.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.9.3	The contractor with jurisdiction to complete the penalty waiver determination 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 relevant conditions of Requirement 3898.2 have been met.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.9.3.1	The contractor shall, if the provider or supplier’s request does not furnish sufficient information to make a determination on each such condition, advise the provider or supplier of all such insufficiencies, advise that the provider or supplier has the burden of proof and of production of evidence to show that §903(c) applies in the particular circumstance, and advise that sufficient information must be supplied within 45 days or the penalty waiver request will be denied.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3898.9.3.2	Notwithstanding the specifications of Requirement 3898.9.3.1, the contractor should, at its sole discretion, take notice of any relevant and material fact of which it is aware that is not subject to reasonable dispute.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.9.3.3	If sufficient information is not supplied within the allotted 45-day period, the contractor shall terminate the penalty waiver determination and proceed with the process for assessing the penalty without further delay.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.9.3.4	Notwithstanding the specifications of Requirement 3898.9.3.3, the contractor should, at its sole discretion, grant an extension of time to the provider or supplier to furnish sufficient information.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.9.4	The contractor shall consider the penalty waiver issue to be moot insofar as the particular provider or supplier is concerned if, at any stage of the penalty waiver determination process, the contractor or other entity determines that the penalty at issue will not be imposed on a basis other than §903(c).	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.9.5	Unless the §903(c) penalty waiver determination is terminated on a basis specified in Requirement 3898.9.1 through Requirement 3898.9.4, the contractor shall make determinations on each of the remaining seven conditions specified in Requirement 3898.2, in accordance with the standards specified in Requirements 3898.3.2 through 3.8.5.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.9.5.1	The contractor shall complete a determination on each such condition notwithstanding that the contractor determines that one or more conditions are not met.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.9.6	The contractor shall complete the penalty waiver determination within 60 days of receipt of the provider or supplier’s request for a penalty waiver determination or within 45 days	X	X	X	X					PSCs, MIP contractors under §1893 of the Act

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
	of receiving an error-only determination from another entity, whichever is longer.									
3898.9.6.1	The contractor, in calculating the foregoing performance deadlines, shall not consider delays caused by a provider or supplier’s failure to furnish sufficient information, by the failure of another entity to make a proper and timely referral of a matter, by the failure of CMS to clarify proper jurisdiction in a particular matter, or for other good cause shown.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.9.6.2	If the contractor cannot complete the determination within the applicable deadline as specified in Requirement 3898.9.6, the contractor shall notify the provider or supplier of the delay within such applicable deadline, take no action to impose the penalty at issue, and seek to resolve the issues causing the delay.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.9.6.3	If the contractor determines that each of the eight conditions specified in Requirement 3898.2 have been met, then the contractor shall implement Requirement 3898.1.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.9.6.4	If the contractor determines that any one of the eight conditions specified in Requirement 3898.2 is not met, then the contractor shall not implement Requirement 3898.1.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.10	The contractor shall furnish notice of the penalty waiver determination to the provider or supplier.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.10.1	If the determination is adverse to the provider or supplier in whole or in part, the contractor shall include in such notice an explanation of the basis for such adverse determination.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3898.10.2	The contractor shall include in all such notices statements: a) that if the provider or supplier believes that the penalty waiver determination is adverse to the provider or supplier, the provider or supplier has a right to request a reconsideration of such determination; b) of the means for making such a request; c) specifying the deadline for making such a request (which deadline shall not be less than 60 days of such notice); and d) that the provider or supplier may also request a hearing and present written evidence and arguments.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.11	The contractor shall reconsider its penalty waiver determination upon receipt of the provider or supplier’s timely request to do so.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.11.1	The contractor shall not reconsider the penalty waiver determination if, on other grounds, the contractor has determined that the penalty will be rescinded or that a penalty will not be imposed.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.11.2	The contractor shall furnish the provider or supplier with an opportunity to be heard if a request to do so is timely made by the provider or supplier.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.11.3	The contractor shall furnish the provider or supplier with an opportunity to present written evidence and arguments, provided the provider or supplier presents such material within 30 days of requesting the reconsideration or within 10 days of any hearing on the matter, whichever is later.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3898.11.4	The contractor shall complete the reconsideration of its penalty waiver determination within 30 days of receiving the provider or supplier’s timely request to do so, of any hearing that may be conducted on the matter, or of any filing of written arguments or evidence on the matter, whichever is later.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.11.5	The contractor shall complete the reconsideration of its penalty waiver determination in accordance with the policies established by this transmittal.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.11.6	The contractor shall furnish notice of its reconsideration to the provider or supplier.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.12	The contractor shall compile a record of each §903(c) penalty waiver determination.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.12.1	The contractor shall include in such record all relevant documentary material regardless of form or format.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.12.2	The contractor shall maintain and dispose of such record in accordance with such record retention policies and procedures as apply to the maintenance of the associated penalty record.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.12.3	With respect to records of matters that were transferred, or for which the contractor has no associated penalty record, the contractor shall maintain and dispose of such records in accordance with such record retention policies and procedures as apply to the maintenance of claims records.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
F I S S	M C S					V M S	C W F			
3898.13	The contractor shall report §903(c) penalty waiver activity on a quarterly basis in accordance with the instructions specified in Appendices A & B to this transmittal and in the Excel® formats represented by the Attachments to those Appendices.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.13.1	The contractor shall, unless a particular error was previously reported by the contractor, or unless CMS has notified the contractor of such particular error, append to the quarterly report documentation of each error that is identified therein. NOTE: Contractor-issued erroneous program guidance will not be considered in Contractor Performance Evaluation at this time.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.14	In addition to addressing the penalty waiver case in accordance with the foregoing requirements, if the contractor is aware of other adverse, or potentially adverse, effects of an erroneous guidance on other providers or suppliers, then the contractor shall take appropriate corrective action to eliminate or mitigate the effects of any such erroneous guidance that it or another entity has issued, consulting its RO or project officer as appropriate.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.15	Each regional office shall provide to the pre-implementation contacts in §V below, the name, telephone number, and email address of a contact person to assist CO in the implementation of this instruction.									Regional Offices
3898.15.1	Each contact person provided in 3898.15 shall act as a Point Of Contact for contractor inquiries regarding the implementation of the penalty waiver policy and coordinate with Central Office (CO) regarding resolution of such issues.									Regional Offices

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
					F I S S	M C S	V M S	C W F		
3898.16	A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "Medlearn Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into any educational event on this topic.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act
3898.16.1	Contractors may utilize the Questions and Answers contained in Appendix C as job aids for responding to enquiries from the provider community.	X	X	X	X					PSCs, MIP contractors under §1893 of the Act

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions:

X-Ref Requirement #	Instructions
3898.Appendix A	Instructions for completing the Quarterly Report of Penalty Waiver Activities (with mockup of the report format)
3898.Appendix B	Instructions for completing the Quarterly Summary Report of Penalty Waiver Activities (with mockup of the report format)
3898.Appendix C	Frequently Asked Questions About Penalty Waiver Based on Erroneous Guidance

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

<p>Effective Date*: July 24, 2003</p> <p>Implementation Date: January 19, 2006</p> <p>Pre-Implementation Contact(s): Angela Costello, email: angela.costello@cms.hhs.gov</p> <p>or Tracey Hemphill, email: tracey.hemphill@cms.hhs.gov</p> <p>Post-Implementation Contact(s): Appropriate Regional Office</p>	<p>No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2006 operating budgets.</p>
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3 Attachments

Instructions for the Quarterly Report of Penalty Waiver Activities

Introduction

This report form is furnished in Excel® format. There are twelve fields to be completed by the contractor. The first two fields, **Contractor Name/Number** and **Quarter Ending**, do not, presumably, require elaboration. General instructions follow immediately. Instructions for the remaining ten fields are addressed in the field-specific section.

General Instructions

1. Download the Excel® report format from www.cms.hhs.gov/contractors/erroneousguidance/default.asp and use this format to report your penalty waiver activities.
2. Report all actions. That is, report transfers, error-only determinations, “completed” determinations, and reconsiderations. You may, if you wish, segregate these actions on separate Excel® sheets. If you elect to do so, amend the first row of the sheet to add the subtype of activity for each sheet.
3. Report as a transfer any case for which you do not have any jurisdiction and have completed the transfer. Do not report a case where you believe, but have not yet confirmed, that you do not have jurisdiction.
4. Report as an error-only determination any case where you have completed the error determination and forwarded the case to the entity with jurisdiction to complete the penalty waiver determination.
5. Do not report twice an action where you both determined that error was present and then completed the penalty waiver analysis. Report this case only once as a completed determination.
6. Report as a completed penalty waiver determination, a case where you found no §903(c)-type error and where you have jurisdiction to complete the penalty waiver determination.
7. Include as a completed penalty waiver determination any case that is closed due to a lack of ripeness, due to insufficiency of information from the provider or supplier, or due to mootness.
8. In accordance with Requirement 3898.13.1, unless a particular error was previously reported by the contractor or unless notice of such error has been furnished to the contractor, the contractor must attach documentation of each error identified in an error-only determination, in a completed determination, or, if not previously acknowledged, in a reconsideration.
9. The report must be completed quarterly in the Excel® report format and submitted on either a 3½” floppy disk or as an attached file to an email and sent (with a copy to your project officer) to: Kenneth Bavaria, Division of Performance Evaluation Operations, Medicare Contractor

Management Group, Center for Medicare Management, Mailstop S2-21-28, 7500 Security Boulevard, Baltimore, Maryland 21244 or to kenneth.bavaria@cms.hhs.gov.

10. If you have questions concerning these reporting instructions, contact Angela Costello, Provider Billing Group, at 410-786-1554 or at angela.costello@cms.hhs.gov.

Field-Specific Instructions

1. **Provider Name & Number:** Ensure that the name of the provider or supplier, and its corresponding Medicare provider number, match the name and number shown on your penalty record.
2. **Date In:** The date you received the request for a waiver or for reconsideration, or received a transfer case, or received a referred case under a specific delegation.
3. **Date Out:** The date you issued your decision.
4. **> D:** Mark w/ an “X” if the original action took longer than 60 days to complete or if a reconsideration took longer than 30 days to complete.
5. **Penalty:** This field is for identifying the penalty at issue. Specify a pithy label or cite to a regulation, a statute, or a manual provision (in that order of preference). Labels may be standardized in the future based on your input.
6. **Type of Action:** This field is for coding the type of action. Use the following codes:
T (transfer);
EOD (error-only determination);
CD (completed determination); or
R (reconsideration).
7. **Basis of Decision:** Insert a phrase that describes the basis of your decision. If an error has been determined, a citation should be given that identifies the document where the error may be found. If the error was in a program transmittal, cite to the Transmittal and CR numbers, and, if feasible, also to the page, paragraph, and line numbers. For example: Trans. 888, CR 9999, p.3, ¶ 2, line 4.
8. **Decision:** Enter the following codes to identify the outcome of your determination:
 - For transfers (T): Enter NJ (no jurisdiction);
 - For error-only determinations (EOD): Enter E (error) or NE (no error);
 - For completed determinations with no waiver granted: Enter WD (waiver denied) plus the number of the condition that was not met (1 through 8 – see Requirement 3898.2) or R (not ripe), or I (insufficient information), or M (moot).
 - For completed determinations granting a waiver, enter the amount of the waiver.
(This field is defined as a currency number with no decimal points and will accept 8-figure amounts. Round to the nearest dollar. Commas are not necessary, as Excel® will insert them. The entry of codes in this field will not affect the calculation of the total for this column.)
9. **Re:** This field is used in conjunction with the “Annotations” field to specify which item is being addressed.
10. **Annotations:** This field is optional. Contractors may wish to annotate the report by elaborating on a particular case.

Quarterly Report of Penalty Waiver Activities

CONTRACTOR NAME/NUMBER:

QUARTER ENDING:

Item	Provider Name and Number	Date In	Date Out	> D	Penalty	Type of Action	Basis of Decision	Decision
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
21								
22								
23								
24								
25								
							Total of Waivers Granted	\$0

Re Annotations

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Instructions for the Quarterly Summary of Penalty Waiver Activities

General Instructions

Download the Excel® report format from www.cms.hhs.gov/contractors/erroneousguidance/default.asp and use this format to report your summary of penalty waiver activities.

There are four general fields in the report. The first three fields, **Contractor Name / Number, For Quarter Ending**, and **Date of Report** do not, presumably, require elaboration. The fourth field, **Contact**, must include the name, telephone number, and e-mail address of an individual who can respond to CMS inquiries concerning both the report and the contractor's penalty waiver activities generally.

Include data for both the reporting quarter and for the year to date. Use the Federal fiscal year for the purpose of reporting YTD data.

Submit a separate report for each contractor jurisdiction. For example:

- Each DMERC shall submit a separate report for each region.
- Each local carrier shall submit a separate report for each state or sub-state.
- Each FI shall submit a separate report for each state or sub-state.
- Each RHHI shall submit a separate report for each region.

The report must be completed quarterly in the Excel® report format and submitted on either a 3½" floppy disk or as an attached file to an email and sent (with a copy to your project officer) to:

Kenneth Bavaria, Division of Performance Evaluation Operations, Medicare Contractor Management Group, Center for Medicare Management, Mailstop S2-21-28, 7500 Security Boulevard, Baltimore, Maryland 21244 or to kenneth.bavaria@cms.hhs.gov.

If you have questions concerning these reporting instructions, contact Angela Costello, Provider Billing Group, at 410-786-1554 or at angela.costello@cms.hhs.gov.

Instructions for Specific Report Items

This report has 35 fields to address specific actions/outcomes. Although the titles of some of the items may appear to be self-explanatory, express instructions are included for each item. Items 18, 20, and 34 require dollar values. All remaining items require a count. The data entry cells for items 3, 7, 8, 24, 28, and 29 are defined in Excel® with formulas that will produce the correct amount.

Item	Reporting Activity	Instruction
1	Cases Pending From Prior Period	Report zero for the first report. For subsequent reports use the count from item 8 of the prior quarterly report.
2	New Cases	Report all cases received during the quarter regardless of source.
3	Total Prior Pending and New Cases	No entry required; Excel will add items 1 & 2.
4	Cases Transferred	These are cases that you transfer to another entity for jurisdictional reasons. Do not count cases that you refer for an error-only determination, i.e., cases where you have jurisdiction to complete the determination but another entity will complete the error determination. Keep these cases as pending.
5	Cases Withdrawn	This item is for cases withdrawn by the provider or supplier.
6	Determinations Made	The number of completed determinations. This count should equal the sum of items 9, 10, and 11.
7	Total Actions Completed	No entry required; Excel will add items 4, 5, & 6.
8	Cases Pending At End of Period	No entry required; Excel will subtract item 7 from item 3.
9	Error-Only Determinations Made	This item is for a count of those cases where you have jurisdiction only for the error determination (and have completed such error determination). Do not count cases where you also have jurisdiction to complete the determination but have not yet done so.
10	Completing-Only Determinations Made	This item is for a count of those cases where you have jurisdiction only to complete the determination, some other entity has completed the error determination (and found error and then referred the matter to you), and you then have completed the §903(c) determination.
11	Full Determinations Made	This item is for a count of those cases where you have jurisdiction to both make an error determination and to complete the §903(c) determination and you then have completed the determination. Note that if you find no error in a case where you have dual jurisdiction, you may complete the determination without considering whether other conditions were met. Such cases should be counted here.

**Instructions Continued for
The Quarterly Summary Report**

12	No-Error	This item should include cases from items 9 and 11 where you found no error.
13	Error But Not Ripe	This item should include applicable cases from items 10 and 11.
14	Error But Insufficient Information	This item should include applicable cases from items 10 and 11
15	Error But Moot	This item should include applicable cases from items 10 and 11
16	Error But Other Condition Not Met	This item should include applicable cases from items 10 and 11
17	Waivers Denied	This item should include applicable cases from items 10 and 11. It reflects all cases included in items 13, 14, 15, & 16, as well as those cases from item 12 for which you also had jurisdiction to make the error determination.
18	Value of Waivers Denied	The dollar value of the cases included in item 17.
19	Waivers Granted	This item should include all cases from items 10 and 11 that are not included in item 17.
20	Value of Waivers Granted	The dollar value of the cases included in item 19.
21	Cases Pending More Than 60 Days	This count should include both cases from item 8 as well as any case from items 4 or 6 that was older than 60 days when the action was completed.
22	Reconsiderations Pending From Prior Period	Report zero for the first report. For subsequent reports use the count from item 29 of the prior quarterly report.
23	New Reconsiderations	Report all new requests for reconsideration of determinations you have made.
24	Total Prior Pending and New Reconsiderations	No entry required; Excel will add items 22 & 23.
25	Reconsiderations Transferred	These are requests for reconsideration of a determination that you did not make or for which you have not otherwise been delegated the authority to address and that you transferred to another entity. Do not count reconsideration cases where the nature of the request involves both error reconsideration and other-condition reconsideration and that you have referred the former to another entity because you do not have jurisdiction to consider error. Keep these cases as pending until the error reconsideration is made and the matter is re-referred to you.
26	Reconsiderations Withdrawn	This item is for reconsideration requests withdrawn by the provider or supplier.

**Instructions Continued for
The Quarterly Summary Report**

27	Reconsiderations Made	The number of completed reconsiderations. This count will equal the sum of items 30, 31, and 32.
28	Total Reconsideration Actions Completed	No entry required; Excel will add items 25, 26 & 27.
29	Reconsiderations Pending At End of Period	No entry required; Excel will subtract item 28 from item 24.
30	Determinations Affirmed	Include only those reconsiderations cases from item 27 where you ratify your original determination. Include in this count any reconsideration case where, although you may have amended your original determination with respect to a particular issue, your reconsideration determination leaves untouched the final conclusion of such original determination as to whether a waiver shall be granted and, if so, as to the amount of the penalty to be waived.
31	Determinations Modified	Include only those reconsiderations cases from item 27 where you partially reverse your original determination, i.e., where you originally granted a partial waiver of the penalty and have now, upon reconsideration, determined to grant a waiver of the full amount of the penalty.
32	Determinations Reversed	Include only those reconsiderations cases from item 27 where you fully reverse your original determination, i.e., where you originally denied granting a waiver of the penalty and have now, upon reconsideration granted a waiver in whole or in part.
33	Waivers Granted	This item should include reconsideration cases from items 31 and 32 where a full or partial was granted. The count should not include cases where a partial waiver was granted in the original but not increased upon reconsideration.
34	Value of Waivers Granted	The dollar value of the reconsideration cases included in item 33.
35	Reconsiderations Pending More Than 60 Days	This count should include both reconsideration cases from item 29 as well as any reconsideration case from items 25 or 27 that was older than 60 days when the action was completed.

Quarterly Summary Report of Penalty Waiver Activities			
CONTRACTOR NAME/NUMBER:			
FOR QUARTER ENDING:			
DATE OF REPORT:			
CONTACT:			
Item	Category	Reporting Quarter	Year To Date
1	Cases Pending From Prior Period		
2	New Cases		
3	Total Prior Pending and New Cases	0	0
4	Cases Transferred		
5	Cases Withdrawn		
6	Determinations Made		
7	Total Actions Completed	0	0
8	Cases Pending At End of Period	0	0
9	Error-Only Determinations Made		
10	Completing-Only Determinations Made		
11	Full Determinations Made		
12	No-Error		
13	Error But Not Ripe		
14	Error But Insufficient Information		
15	Error But Moot		
16	Error But Other Condition Not Met		
17	Waivers Denied		
18	Value of Waivers Denied		
19	Waivers Granted		
20	Value of Waivers Granted		
21	Cases Pending More Than 60 Days		
22	Reconsiderations Pending From Prior Period		
23	New Reconsiderations		
24	Total Prior Pending and New Reconsiderations	0	0
25	Reconsiderations Transferred		
26	Reconsiderations Withdrawn		
27	Reconsiderations Made		
28	Total Reconsideration Actions Completed	0	0
29	Reconsiderations Pending At End of Period	0	0
30	Determinations Affirmed		
31	Determinations Modified		
32	Determinations Reversed		
33	Waivers Granted		
34	Value of Waivers Granted		
35	Reconsiderations Pending More Than 60 Days		

Frequently Asked Questions About Penalty Waiver Based on Erroneous Guidance

1. Question: The effective date of this policy is July 24, 2003. Does that mean that every penalty imposed after that date is subject to this policy?

Answer: No. The policy applies to erroneous guidance issued on or after July 24, 2003. Because there would be an interval of time between when a particular erroneous guidance was issued and the act or omission in following such guidance that was the cause of Medicare imposing the penalty, it is not likely that a penalty imposed shortly after July 24, 2003 would be within the scope of this policy. Note, however, that certain actions that occurred earlier than the effective date of this policy could become indirectly affected by it. For example, consider a service furnished prior to the effective date, an erroneous guidance issued on or after the effective date relating to the filing of a claim for such service, an act or omission relating to the filing of such claim, and the imposition of a penalty based on such act or omission. In this circumstance, assuming the requirements of the policy are otherwise fully met, it would be appropriate to waive the penalty, thus indirectly affecting the provider or supplier's actions (i.e., in furnishing the service) that predate the effective date of the policy.

2. Question: Given that this policy was issued long after the effective date, will Medicare apply this policy retroactively to waive a penalty?

Answer: Yes. If a provider or supplier can show that its act or omission that was the basis of a contractor imposed penalty was caused by following erroneous written Medicare guidance issued on or after July, 24, 2003, the contractor will retroactively waive the penalty if the requirements of the policy are met. A provider or supplier that believes it may qualify for a retroactive penalty waiver under this policy should contact the contractor that imposed the penalty.

3. Question: This policy applies only to certain "Medicare contractors". What about penalties imposed directly by the Centers for Medicare and Medicaid Services (CMS) or by the Office of the Inspector General (OIG)?

Answer: The instructions issued to Medicare contractors via CR 3898, as well as the accompanying manual provisions, apply only to the types of Medicare contractors specified in the transmittal. However, §903(c) of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003, which amended §1871(e)(2) of the Social Security Act (the Act), also applies to penalties imposed directly by CMS. A provider or supplier, which believes that a penalty imposed by a CMS component qualifies for waiver under the statute, should contact the component that issued the penalty. Similarly, one should contact the OIG for matters concerning penalties imposed by the OIG.

4. Question: The transmittal does not include a definitive list of penalties that are subject to the penalty waiver policy. How can I determine if a particular penalty is within the scope of the policy?

Answer: As a start, determine the entity (OIG, CMS component, or a Medicare contractor) that took the action, or that has given notice of the intent to take an action, and then contact that entity for additional information. If a Medicare contractor has jurisdiction for the action, then that contractor will advise you whether the action qualifies as a penalty within the scope of the transmittal. More definitive guidance regarding what is, and what is not, a penalty will be forthcoming. In the meantime, it is worth noting that actions that are not “penalties” include but are not necessarily limited to the following: a rejection or a “return-to-provider” action on a claim or bill, an initial determination on a claim or bill, a redetermination or a reconsideration of such initial determination, a contractor hearing decision regarding such initial determination, a national coverage decision, a local coverage decision, a determination made pursuant to a local medical review policy, a coding decision, an enrollment decision by a contractor (including the National Supplier Clearinghouse), a notice of program reimbursement, an overpayment, accrued interest on an unsatisfied overpayment (although such interest may also be waived under MMA §903(c), but such a waiver is not within the scope of the penalty waiver policy), a CMS Ruling, a Medicare fee schedule amount or other allowed amount, the amount of Medicare payment for a covered item or service, a determination regarding whether a matter is within the scope of this transmittal, 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.

5. Question: Section 903(c) of the MMA also mandates that Medicare waive interest when the debt on which the interest was based resulted from following erroneous Medicare program guidance. Is interest within the penalty waiver policy and, if not, when will interest be addressed?

Answer: Although §903(c) of the MMA also mandates that Medicare waive interest when the debt on which the interest has accrued resulted from following erroneous Medicare program guidance, such waiver of interest is not within the scope of the penalty waiver policy. Waiver of interest will be addressed separately. If a provider or supplier believes that a particular assessment of interest is “waivable” under the statute, it should contact the contractor or CMS component that gave notice of the overpayment.

6. Question: I was told by Medicare to follow a certain course of action and then I was penalized for doing so. But I have nothing in writing. Can I still get a waiver?

Answer: No, not unless what you were told to do is in writing and that writing is erroneous on its face. The policy follows the statute in limiting the penalty waiver to matters that resulted from following written erroneous guidance.

7. Question: I received written guidance from CMS’ Central Office and followed it. But then my contractor imposed a penalty when I followed the guidance. Where do I go for a waiver?

Answer: Contact the entity that imposed or has given notice of the intent to impose the penalty. In your circumstance, contact the contractor that imposed the penalty.

8. Question: I've received a notice from my contractor that it intends to impose a penalty. I believe that I followed the contractor's written guidance which, apparently, was erroneous. Should I contest the penalty itself or seek a penalty waiver?

Answer: We cannot recommend what specific course of action, if any, you should take. However, we can advise that Medicare policy allows a provider or supplier to both contest the penalty itself and to seek a penalty waiver or to pursue only one of these actions. We recommend that you consider obtaining competent legal counsel to assist you.

9. Question: I don't understand the policy as it relates to jurisdiction. Please explain.

Answer: The policy was designed so that the entity that issued the guidance determines whether the guidance was erroneous and the entity that imposed, or that intends to impose, the penalty determines whether all of the other requirements for waiver have been met. The jurisdictional rules are intended to achieve that effect. Requests for a waiver of a penalty should always be directed to the entity that imposed, or that has furnished notice of the intent to impose, the penalty. The provider or supplier needn't identify the entity that issued the guidance upon which the provider or supplier relied, although doing is likely to expedite matters.

10. Question: Given the delay in implementing this statutory provision, I can't possibly meet the requirement for timely requesting a waiver of the penalty. Do I have any options?

Answer: Yes. A provider or supplier that was precluded from filing a timely request for a penalty waiver due to the delay in issuing this policy may yet perfect such a request by submitting same to the Medicare contractor that imposed the penalty within 120 days of the issuance of CR 3898. This transition policy does not apply to penalties imposed by other entities; contact those entities for additional information.

11. Question: Does the penalty waiver policy apply to beneficiaries?

Answer: No. The penalty waiver policy does not apply to Medicare beneficiaries because the Congress explicitly addressed the policy to providers and suppliers only. A beneficiary who believes he/she has been improperly penalized should contact the entity that imposed the penalty and explain his or her circumstances. The beneficiary may also wish to consider obtaining competent legal counsel for assistance.

12. Question: Does the penalty waiver provision apply to Medicare+Choice organizations, Medicare Advantage Organizations, or Prescription Drug Program Sponsors?

Answer: No. The Congress identified only providers and suppliers as subject to the penalty waiver policy. Given that these are Medicare fee-for-service terms of art, we do not believe that the penalty waiver policy applies to Medicare+Choice

organizations, Medicare advantage organizations, or Prescription Drug Program Sponsors. That is not to say that any such organization that is adversely affected by erroneous program guidance would be without recourse. Rather, it means merely that such organizations would not be bound by the formalistic processes made necessary by MMA §903(c).

13. Question: I believe that Medicare erred in imposing a penalty on me. Does the penalty waiver policy of CR 3898 address this scenario?

Answer: No. The penalty waiver policy may not be invoked to challenge a penalty on the basis that there was an error in imposing a penalty. The appeal process associated with the penalty is the proper (and only) means to address such claim of error. The penalty waiver policy of CR 3898 may be invoked only when a penalty was imposed or is pending imposition by a Medicare contractor based on a provider or supplier's act or omission that resulted from following erroneous written Medicare program guidance. The penalty waiver policy should not be invoked when the provider or supplier cannot plausibly assert that its act or omission was the result of following such erroneous guidance.

14. Question: What is the deadline for requesting a waiver of a penalty under the policies of CR3898?

Answer: There is no single, standard deadline for requesting a waiver of a penalty under this policy. Because the penalty waiver policy applies to different types of penalties, and because each type of penalty determination may have its own unique process, and because this policy must be implemented by several different types of contractors, we have not specified a single standard for the deadline for the provider or supplier to request a penalty waiver because such single standard might not fit well into the multiplicity of penalty determination processes. Thus, we have instructed our contractors to specify a deadline that is congruent with the associated penalty determination or penalty appeal process, as applicable. We believe that this approach will better serve all parties to these processes than would a single, centrally-imposed standard.

15. Question: If Medicare grants a waiver of the penalty (because I followed erroneous program guidance and otherwise met the requirements of CR 3898, will Medicare make me whole from the effects of having imposed the penalty (or reimburse me for the costs incurred in obtaining such waiver)?

Answer: No, generally not. The Congress did not grant any authority to make adjustments for the adverse effects of having imposed a penalty on a provider or supplier for acts or omissions that resulted from following erroneous Medicare program guidance. However, contractors may invoke any existing Medicare fee-for-service authority (for which they possess a delegation) to mitigate the adverse effects of a penalty that has been waived under the authority of CR 3898. For example, a contractor may use its reopening authority to re-adjudicate a claim or may extend the time available for the timely filing of a claim if such actions were warranted in a particular circumstance. Medicare will not reimburse a provider or supplier for costs associated with requesting and pursuing a penalty waiver.

16. Question: The reconsideration and appeals processes seem to be inconsistent with both existing and proposed contractor appeals processes. In addition, no mention is made of appeals to administrative law judges. Please clarify.

Answer: The administrative appeal process for penalty waiver determinations is separate and distinct from all other Medicare fee-for-service appeal processes. The terms “reconsideration” and “appeal”, as used in the context of the penalty waiver process, are used because they are terms that are familiar to the provider community not because they “track” or are otherwise consistent with other fee-for-service appeal processes. There is only a single, one-step appeal process for challenging a penalty waiver determination and it is called “reconsideration”. Reconsideration may include a hearing (upon timely request) but the hearing is not a separate or second-level appeal process; it is, when invoked by the provider or supplier, part of the contractor’s reconsideration of its own penalty waiver determination.

17. Question: Given that reconsideration is the contractor’s “second look” at its own penalty waiver determination, and given that I can submit written arguments, affidavits, and other written evidence for the contractor’s review, what utility is there for me in a hearing?

Answer: We assume that, in most cases, providers and suppliers will conclude that a hearing is of little, if any, utility in pursuing a reconsideration of the penalty waiver determination. However, in a few cases the provider or supplier may feel that its in-person testimony may be persuasive on a particular issue. But we assume that, in most cases, testimonial or demonstrative evidence would not have much, if any, utility. Nevertheless, it is the provider or supplier’s option as to whether to request a hearing on a particular matter.

18. Question: The policy states that not only must the guidance be erroneous but the error must also be “material”. Can you furnish an example of when erroneous guidance would not be material?

Answer: As the policy states, a material error is one in which the error is the “necessary cause” of the provider or supplier’s act or omission that gave rise to the penalty. The following example, made intentionally extreme for the purpose of making the point clear, may be helpful. If a particular guidance addressed a variety of topics and included an error regarding hospital billing for a particular diagnosis, but the provider or supplier’s act or omission related to billing for ambulance mileage (and the guidance was accurate regarding billing for ambulance mileage), then the error in the guidance with respect to hospital billing could not have been the necessary cause of the provider or supplier’s act or omission with respect to billing ambulance mileage. We recognize that questions of materiality are not likely to be so clear cut as the foregoing example. Perhaps the better way to consider the issue of materiality is to ask the question: “Was it the error in the guidance that caused the provider or supplier to act, or to refrain from acting, in the manner it did?” If the contractor concludes that the error would have caused a reasonable provider or supplier to act or to refrain from acting in the manner it did, then the materiality factor is met.

19. Question: What factors would alert me to the fact that a contractor was acting outside the scope of its authority in issuing a particular guidance?

Answer: There is no definitive list of factors that would cause a provider or supplier to know that a contractor was acting outside the scope of its authority in issuing a particular guidance. One must consider the totality of the circumstances in evaluating whether the “within-scope-of-authority” requirement is potentially relevant. An example when a provider or supplier should question whether a contractor was acting within the scope of its authority would be if a carrier advised a hospital that it could submit claims to the carrier rather than to the hospital’s intermediary. This extremely implausible example illustrates the point that a provider must not rely upon such apparently improper guidance without obtaining confirmation that the issuer has the authority to issue such guidance.

20. Question: Would a text message sent to a mobile telephone, a PDA, or other, similar device qualify as a writing?

Answer: No. Our policy is that a text message sent to a mobile device does not qualify as a writing. As text messaging matures as a technology, we will re-evaluate this policy.

21. Question: Can you furnish an example of when a guidance would not relate to an item, a service, or a claim?

Answer: We expect that most Medicare program fee-for-service guidances would relate to an item, a service, or a claim. But certain matters may be so tangential to the furnishing of an item or service or the filing a claim that it would not be reasonable to conclude that the guidance relates to an item, a service, or a claim. One example, to cite an extreme case, would be if the guidance purported to advise on the proper interpretation of a particular State licensure law for a purpose other than meeting Medicare program requirements.

Indeed, many matters for which the legal basis is other than Title XVIII or Title XI of the Social Security Act, might initially be viewed as being outside the scope of item/service/claim. Examples of such matters include: HIPAA compliance, CLIA compliance, copyright infringement (of, e.g., CPT coding and descriptors), institutional accreditation and individual licensure, State laws and regulations, and Medicaid requirements (except that issues relating to dual eligibility could relate to an item/service/claim) and other similar matters. However, if a particular guidance addressed such matters, then the guidance must be analyzed further to determine whether it also related directly to Medicare fee-for-service. If a Medicare program fee-for-service guidance that addresses such matters also relates, explicitly or implicitly, to the furnishing of an item or service or to the filing of a claim, then such that the guidance would most likely be within the scope of item/service/claim.

22. Question: If an erroneous guidance was issued before July 24, 2003 but remained in effect after that date, and if I followed the guidance after July 24, 2003 and a penalty was thereafter imposed upon me, can I rely upon this policy to obtain a penalty waiver.

Answer: In most instances, no. The statute explicitly provides that the guidance must have been issued on or after July 24, 2003. The only circumstance when such a guidance could be within the scope of the policy is when a guidance issued before July 24, 2003 was either re-issued or confirmed in writing on or after that date. Otherwise, a guidance issued prior to the effective date MMA §903(c), even if never rescinded, is outside the scope of the penalty waiver policy.

23. Question: The transmittal requires that I must have “presented circumstances” to the contractor in order to qualify for a penalty waiver. What does this mean?

Answer: The Congress inserted this requirement into the statute to reflect, we believe, the situation where the program guidance in question was issued to a specific provider or supplier in response to a specific situation posed by the provider or supplier. The Congress, we believe, wanted to make sure that when program guidance was provider/supplier-specific and issued in response to a provider or supplier’s request, that the program had received full and accurate particulars from the provider or supplier. Of course, this caution becomes moot when the guidance is issued to providers and suppliers generally, rather than in response to a provider or supplier’s presentation of specific circumstances.

24. Question: With respect to the requirement that I must have followed the guidance, I don’t understand the distinction CMS has made between “substantial but not necessarily complete accord” versus “a small but material deviation”. Please explain.

Answer: The overall purpose of the “followed-the-guidance” requirement is to establish that there must be a nexus between the guidance and the provider or supplier’s act or omission that was the basis for the penalty in question. The two competing standards cited in the question reflect our attempt to balance fairness and rigor when considering whether the requirement has been met. On the one hand, the standard of “substantial-but-not-necessarily-complete-accord” attempts to recognize that it could be unfair to a provider or supplier to deny a penalty waiver for a minor or unimportant deviation from the guidance. On the other hand, the standard of “a-small-but-material-deviation” attempts to recognize that a provider or supplier’s ignoring specific, clear cut instructions (even if erroneous) would be a basis to deny a request for a penalty waiver because, given such a material deviation, it could not be said that the provider or supplier’s act or omission, which was the basis for the penalty in question, was the result of having followed the guidance.

25. Question: Providers and suppliers are compelled to follow Medicare rules if we expect to get paid for furnishing services to your beneficiaries. As such, why are you questioning whether, in a particular instance, it would be reasonable to follow Medicare instructions? Isn’t always reasonable to follow Medicare rules?

Answer: The Congress expressly included a “reasonable reliance” requirement in MMA §903(c). This requirement reflects, we think, that there may be some occasions when it would be unreasonable to rely on a particular guidance. But recognizing that providers and suppliers are expected to follow Medicare rules, we believe that the very fact that the Medicare program issued a guidance creates a

rebuttable presumption that the provider or supplier's reliance on such communication was reasonable. Nevertheless, given that we also recognize that not every communication warrants such a presumption, we've cited several examples when a provider or supplier's reliance on a particular guidance would be misplaced. These include but are not limited to the following circumstances: the communication by its own terms does not purport to be definitive; the communication is informal; the communication was sent by someone that would not appear to have the authority to issue such guidance; the guidance conflicts directly with formal Medicare rules (and does not address the conflict); the guidance conflicts with Medicare's past practices (and does not address such practices); the guidance has been superseded by a formal program issuance; or notice has been issued identifying the guidance in question as being erroneous. We believe that these exceptions reflect a reasonable balance between what a provider or supplier should presume is accurate versus what a provider or supplier should question.

26. Question: What does it mean that "the provider or supplier has the burden of proof and of production of evidence"?

Answer: This language means merely that it's up to the provider or supplier to present to Medicare the facts (production of evidence) that are sufficient to show (burden of proof) that a penalty waiver is warranted.

27. Question: What does "corrective action" mean?

Answer: "Corrective action" in the context of administering the penalty waiver policy simply refers to whatever actions would be appropriate for a contractor to take to both mitigate any adverse effects on the affected provider or supplier and to inform other entities that may have also received the erroneous guidance so as to prevent any adverse consequences to them. Although this instruction to our contractors is to be interpreted broadly, it is, nevertheless, limited to those actions that are within the existing scope of the contractor's delegated authority.

28. Question: Your Requirement 3898.3.1(b) mentions that the error must be material, and then describes what CMS considers to be material. However, the next sentence describes reasonableness, not materiality. Shouldn't this next sentence be placed in Requirement 3898.3.8.3, where reasonableness is discussed?

Answer: No. The use of the term "reasonable" in the discussion of materiality is intentional and the standard that is being established in 3898.3.1(b) is distinct from that described in 3898.3.8.3.

Requirement 3898.3.1(b) speaks to the influence of the error on behavior, whereas 3898.3.8 speaks to the reasonableness of relying on the guidance as a whole. The difference is admittedly a subtle one but, we believe, appropriate. Here's the explanation: Materiality has to do with importance, necessity, influence, or effect. We used the phrase "necessary cause" to capture the essence of materiality in the context of contractors determining whether the error was important or not. That is, did the error really cause the provider or supplier to act (or refrain from acting) in the manner it did or was the error on something so minor or peripheral such that,

even acknowledging the fact of the error, it could not rightly be said to have caused the behavior that became the basis for considering imposing a penalty? The second sentence of this requirement, which contains the reference to “reasonable”, furnishes the standard by which the contractor is to go about making this judgment. What the sub-requirement asks the contractor to do is to mentally put itself in the shoes of the provider or supplier at the time the provider or supplier received the guidance so as to evaluate whether the provider or supplier would have been misled by the error. But because a contractor cannot know how any particular provider or supplier might have processed the erroneous material, we supplied a “reasonable person” standard, or in this case a reasonable provider or supplier standard, by which contractors are to make this judgment. So, this sub-requirement mandates that the contractor ask itself: Would a reasonable provider or supplier have been misled by the error to act or to refrain from acting in the manner it did, or was the error so minor, so peripheral, or so inconsequential that a reasonable provider or supplier would not have been sufficiently influenced by the error to produce the behavior that is now the subject of a penalty. In a sense, this is a micro-analysis of the importance of the error on the provider or supplier’s behavior.

In contrast, 3898.3.8 speaks to whether it was reasonable for the provider or supplier to rely upon the guidance as a whole. That is, separate from the question of the importance of the error itself, is the question: Was the guidance so clearly flawed or otherwise suspect that it should not have been relied upon? Sub-requirements 3898.3.8.1, 3898.3.8.2, 3898.3.8.3, and 3898.3.8.4, each of which makes reference to “reasonableness” in one context or another, plus sub-requirement 3898.3.8.5, are intended to furnish specific standards or situations to guide the contractor in answering this separate question. Sub-requirement 3898.3.8.3, to which you cite, speaks to the appearance of accuracy of the guidance as a whole as opposed to the importance of the error, which is the subject addressed in 3898.3.1(b). So, assuming the existence of a material error, sub-requirement 3898.3.8.3 tells the contractor to ask itself: Although this guidance contains a material error, such that a reasonable provider or supplier would have been misled by the error itself, was the guidance as a whole sufficiently suspect or flawed such that a reasonable provider or supplier should not have relied on this guidance?

29. Question: CMS has said that its contractors shall not construe the term “penalty” so broadly as to include the following types of actions: a rejection or a “return-to-provider” action 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, a local coverage decision, a determination made pursuant to a local medical review policy, a coding decision, an enrollment decision by a contractor (including the National Supplier Clearinghouse), a notice of program reimbursement, 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 transmittal, 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.

But these are the very types of matters for which I'm likely to receive poor guidance. Isn't it unfair to exclude these matters from the penalty waiver policy?

Answer: The language you refer to merely addresses matters that are not penalties; it doesn't exclude from the penalty waiver policy matters that could be the subject of an erroneous guidance. These are entirely different matters. For example, although a coding decision is not a penalty, it could be the subject of an erroneous guidance. If it were the subject of an erroneous guidance, and if a provider or supplier were thereafter subject to some type of penalty (by a Medicare contractor) for having followed such erroneous guidance, then the erroneous guidance would clearly be within the scope of the policy of CR 3898 and a penalty waiver would be appropriate if all the remaining conditions are also met.

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 a fiscal intermediary (including a Regional Home Health Intermediary (RHHI)), a Carrier (including a Durable Medical Equipment Regional Carrier (DMERC)), 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 RHHI, may not presume that a DMERC may instruct such agencies in matters related to claim submission (without some further explanation regarding the DMERC'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 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).