CMS-6272-IFC-3 Medicare Secondary Payer (MSP) Amendments

Submitter : **Mr. Bruce Shirk** **Date & Time:** **04/20/2006**

Organization : **Powell Goldstein LLP**

Category : **Attorney/Law Firm**

Issue Areas/Comments

MMA Amendments to the Medicare Secondary Payer Provisions

MMA Amendments to the Medicare Secondary Payer Provisions

See Attached

CMS-6272-IFC-3-Attach-1.DOC

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April 20, 2006

SUBMITTED ELECTRONICALLY

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6272-IFC, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: ***File Code CMS-6272-IFC***; Interim Final Rule Implementing MMA Amendments to the Medicare Secondary Payer (MSP) Provisions; 42 CFR Part 411, 71 Fed. Reg. 9466-9471 (February 24, 2006)

To Whom It May Concern:

This letter submits our comments on provisions of the interim rule relating to the obligation of primary payers under the MSP rules to notify and reimburse Medicare when "it is demonstrated that the primary payer has or had a responsibility to make payment" ("interim rule" § 411.22). We limit our comments to issues of concerns to primary payers who provide or administer insurance under Group Health Plans (GHPs).

We do not attempt in these comments to express views for or against the substantive requirements of the interim rules. Rather, we request that CMS clarify the meaning of certain provisions of the interim rule and, as well, that the agency explain the relationship between certain of the "new" provisions contained in the interim rule and "old" provisions of the regulations that remain in effect but are not addressed in the rule.

We do not make explicit recommendations for changes in the language of the interim rule but recognize that CMS's response to our requests for clarification could require the agency itself to make such changes with concomitant expenditure of resources. With that in mind, we note that the interim rule relates to aspects of existing MSP rules that have long been a source of confusion and operational issues for third party payers: the appropriate mechanisms for compliance with the provisions of 42 CFR § 411.25 that third party payers are to notify CMS

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when they "learn" of a mistaken payment. With the advent of an apparent[1] obligation under Section 411.22 of the interim rule to reimburse CMS directly for mistaken payments before receiving a demand for such payments, third party payers are necessarily wondering whether they must implement operating procedures for direct payment to CMS when, for example, mistaken payments are identified through the VDSA process. Implementation of such procedures will of course have a cost – but third party payers are naturally hesitant to incur that cost until they believe they have a clear understanding of the requirement.

The matters as to which we are requesting clarification are, in brief, as follows:

> The interim rule does not provide guidance as to when primary payers and entities receiving payment from a primary payer are expected to make payment to CMS pursuant to § 411.22
>
> The interim rule does not provide guidance as to how, to whom, and in what form primary payers and entities receiving payment from a primary payer are expected to make payment to CMS.
>
> The interim rule does not address whether entities that receive payment from a primary payer are subject to the notice requirement of § 411.25.
>
> The interim rule is unclear as to what constitutes the phrase "demonstrated . . . responsibility to make payment" in connection with a contractual obligation.
>
> The interim rule does not address whether CMS intends the notice requirements of the current § 411.25 and the current reimbursement obligations of the new § 411.27 to work together or whether the two sections state separate obligations with which payers must separately comply.

[1] In January 2005 CMS personnel with cognizance of the MSP rules told Bruce Shirk of this firm that: (a) CMS understands the MMA to provide that, when a primary payer learns of a conditional payment, it is required to make immediate reimbursement to CMS or its designated contractor and (b) CMS was at that time drafting revisions to the regulations to implement this understanding of the MMA.

A. Interim Rule: Relevant Provisions under Group Health Plans (GHPs)

The interim rule deletes the definition of "third party payer" from § 411.21,[2] replaces it with a definition of the term "primary payer" and provides in the new § 411.22[3] that "a primary payer and an entity that receives payment from [such] a payer must reimburse CMS for any payment if it is demonstrated that the . . . payer has or had a responsibility to make payment".[4] CMS's commentary in the Supplementary Information notes that "[p]rimary payers are *expected* to reimburse CMS *when* it is demonstrated . . . they . . . have . . . payment responsibility"[5] (italics added.) CMS notes that the nomenclature change is being made "to conform to the statutory language under the MMA" and that, [c]onsistent with [this change], we are making nomenclature changes to replace the [term] 'third party payer' . . . throughout subparts B through H" and specifically identifies related changes to § 411.33(f)(4) and §489.20(i)(2)(ii).[6] CMS makes no specific reference to the current § 411.25 which provides that "[i]f a third party payer learns that CMS has made a Medicare primary payment for services for which the third party payer has made or should have made primary payment, it must give notice to that effect to . . . Medicare . . . ."[7]

1. Clarification As To When Primary Payer Must Make Actual Payment To Satisfy Its Reimbursement Obligation Under New § 411.22

CMS's commentary in the Supplementary Information makes clear that primary payers *must* reimburse CMS for conditional payments and that "a primary payer may not extinguish its obligations under the MSP provisions by paying the wrong party . . . when it should have reimbursed . . . Medicare . . ."[8] What is not clear is how and when the primary payer or the entity that received payment from a primary payer is to reimburse Medicare. Some of the language appears to suggest that CMS anticipates that primary payers will reimburse Medicare *immediately and directly* upon a "demonstration" that a given payer has or had primary payment responsibility, thereby relieving CMS and its contractors of the requirement to issue a demand letter. For example, CMS states in the Supplemental Information that "a primary payer may not extinguish its obligations under the MSP provisions by paying the wrong parties, *i.e.,* by paying beneficiaries or providers when they "should have reimbursed" Medicare, thereby implying or appearing to imply that the reimbursement to Medicare would take place in connection with the claims payment process – *i.e.*, at the time the conditional payment is identified – rather than at a

[2] 42 CFR § 411.21 "**Definitions**" (§ 411.21).
[3] 42 CFR § 411.22"**Reimbursement obligations of primary payers and entities that received payment from primary payers**" Interim rule, 42 CFR Part 411, 71 Fed. Reg. 9470 (§ 411.22).
[4] § 411.22(a).
[5] Interim rule, Supplementary Information, 71 Fed. Reg. 9468.
[6] Id.
[7] 42 CFR § 411.25 **Third party payer's notice of mistaken primary payment** (§ 411.25).
[8] Interim rule, Supplementary Information, Fed. Reg. 9468.

later time in response to a demand letter[9]. Similarly, CMS's admonition that primary payers "*are expected* to reimburse CMS *when*" payment responsibility "is demonstrated" can reasonably be understood as requiring the payer to send appropriate amounts to CMS as soon as the conditional payment is identified[10], *i.e.*, *without* waiting for receipt of an MSP demand from the appropriate Medicare contractor. Please clarify whether CMS intends the new § 411.22 to impose such a requirement and, if it does, indicate whether it applies only to primary payers or to both such payers and entities receiving payment from them.

2. <u>Clarification As To Mechanics Of Making Payment If CMS Intends Payer To Satisfy Its Reimbursement Obligation Immediately On Identification Of A Conditional Payment</u>

If it is CMS's intention that a primary payer is to reimburse Medicare immediately as soon as the conditional payment is identified, then primary payers will require direction as to whom and in what form the reimbursement is to be made and, as well, the nature of the supporting information to be provided. It seems clear that, if CMS is to verify that the payer's calculation of the reimbursement has been made in accordance with the requirements of 42 CFR § 411.24, then the information required would include at least the information called out by § 411.25 vis-à-vis the payer's obligation to notify Medicare when a conditional payment is identified. This information includes a description of "the specific situation and circumstances" the type of insurance coverage and, where appropriate, the period during which coverage was effective. If the payer provides such information with the reimbursement, then it would seem that the notice requirements of existing § 411.25 have been satisfied along with the requirements of new § 411.22. Please clarify whether this would be the case and, as well, provide direction as to whom and in what form the reimbursement is to be made.

3. <u>Clarification of Notice Obligations of Entities Receiving Primary Payment</u>

The absence of a specific reference to § 411.25 is confusing because, while CMS's commentary makes clear that the notice provisions of § 411.25 now apply to "primary payers" rather than "third party payers,"[11] the reimbursement requirements of the new § 411.22 extend to

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[9] Interim rule, Supplementary Information. 71 Fed. Reg. 9468.

[10] <u>Id</u>. [italics added]. Note that the language arguably implying immediate and direct payment appears only in the Supplementary Information, not in the text of the interim rule. Nevertheless CMS has used the language and the uncertainty of its intent in doing so arises because the word "when" has a number of meanings. One meaning that is quite reasonable in this context is "just after the moment that < please stop writing ~ the bell rings > <went back to his old job ~ the war ended.>" *Webster's Third New International Dictionary* (1976 ed.), 2602 . This meaning would not be inconsistent with relevant language of the MMA.

[11] "Consistent with these changes [to conform to the language of the MMA] , we are making nomenclature changes to replace the terms 'third party payer,' 'third party payment,' and 'third party plan' with 'primary payer,' 'primary payment,' or 'primary plan, respectively under part 411 throughout subparts B through H." Interim rule, Supplementary Information, 71 Fed. Reg. 9468.

both primary payers *and* entities that receive "payment from a primary payer." Presumably entities that receive rather than make primary payments will from time to time on their own obtain information "demonstrating" that the primary payer had " a responsibility to make payment." These circumstances would require that such an entity notify Medicare of the mistaken or conditional payment. Yet nowhere does the interim rule state that the notice requirements of § 411.25 apply to entities "that [receive] payment from a primary payer." Please clarify whether such entities are subject to the notice requirement of § 411.25.

B. Clarification As To "Demonstration" And Standard of Proof That Conditional Payment Has Been Made

1. A "Contractual Obligation" Cannot Of Itself "Demonstrate" A Responsibility To Make Primary Payment

The new § 411.22 provides that the primary payers' obligation to reimburse CMS arises "if it is *demonstrated* that the primary payer has or had a responsibility to make payment,"[12] noting that the payer's responsibility may be demonstrated by a judgment, compromise, waiver or release or other means, "including but not limited to a settlement, award, or contractual obligation."[13] In this context, the word "demonstrate" means to "manifest clearly, certainly or unmistakably: show clearly the existence of . . ."[14] . The application of this meaning to judgments, compromises, waivers, settlements and awards is clear because such resolutions will necessarily state the obligation of the primary payer to make payment of a specific claim based on the specific facts of and circumstances surrounding *that particular claim.* But it is unclear how a "contractual obligation" – in this case presumably the coordination of benefit provisions of a health plan – can *of itself* "demonstrate" such an obligation as to a particular claim because a contractual obligation is a generic statement of responsibility applicable to all claims. Stated otherwise, the contract sets out the criteria for any primary payer responsibility to make payment of claims generally while judgments, waivers, releases, settlements, awards etc., state or demonstrate that the facts of and circumstances surrounding a particular claim do or do not meet the criteria set out by the contract. But the contract itself cannot "demonstrate" that a particular claim meets its criteria for responsibility to make payment. Some other step must be taken to apply the contract terms to the facts and circumstances of a particular case, e.g., analysis and conclusions evidenced by judgments, formal written settlements, awards, etc. But in the GHP context issues of primary responsibility to pay are usually not resolved by judgments, settlements or awards, etc. Thus the regulation leaves primary payers with no guidance as to how such responsibility is to be demonstrated in the absence of a written compromise, waiver, release,

[12] 42 CFR § 411.22 (a).
[13] 42 CFR §411.22 (b) In this regard, please note that for purposes of this discussion we are focusing on MSP issues arising in connection with GHP and assume that, in this context, the term "contractual obligation" refers to the provisions governing the obligations of a GHP and its beneficiaries.
[14] *Webster's Third New International Dictionary* (1976 ed.), 600.

judgment, settlement, award or the like. Please clarify how "responsibility for payment" is to be demonstrated in such circumstances.

2. Clarification As To The Relationship Between Primary Payer "Learning" Of A Conditional Payment As Specified By Existing § 411.25 And The "Demonstrated" Existence Of A Conditional Payment As Specified By New § 411.22

Effective April 25, 2006, the requirement of § 411.25 that third party payers notify CMS when they "learn" of a conditional payment will be extended to primary payers. CMS has consistently taken the position that "learn" means "is, or should be, aware."[15] This position is binding on primary payers unless a court finds it to be unreasonable in light of the terms of applicable statute. No court has found CMS's view to be unreasonable in the past and, given the relevant terms of the MMA, it is highly unlikely one will do so in the future.[16]

However, the insertion of the new § 411.22 into the MSP rules raises two questions as to the meaning of § 411.25. First, does the obligation to reimburse CMS arise only when responsibility to pay is "demonstrated" in accordance with the terms of § 411.22 or does it also arise when the primary payer "learns" of the existence of a conditional payment pursuant to § 411.25. If the obligation to reimburse arises when the payer "learns" of the conditional payment, then it would seem that the responsibility to pay need not be "demonstrated" in all cases because CMS interprets the word "learns" to include circumstances where the payer "should have known" of the conditional payment which implies a level of knowledge something short of "demonstrated." Second, the existence of two regulatory provisions that separately address what, as a practical matter, is a single fact pattern – in this case the identification of the existence of a previously unrecognized responsibility to make primary payment – is confusing and likely to give rise to claims of ambiguity regarding both the duties of primary payers in such circumstances and the standard of proof required to establish responsibility for payment.

Please clarify the meaning of the word "learns" as used in § 411.25 in light of the term "demonstrated" as used in § 411.22 as related to the standard of proof required. Also please clarify the relationship between the requirement of § 411.25 to notify CMS when a payer "learns" of a conditional payment and the requirement of § 411.25 that a payer "must reimburse CMS . . . if it is demonstrated that the . . . payer has . . . responsibility to make payment", *i.e.*, is the payer supposed to satisfy the notice and reimbursement requirements at the same time or are they separate obligations to be satisfied separately?

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[15] See: *Health Insurance Association of America, Inc. v. Shalala* , 23 F.3d 412, 421 (1994)

[16] "Although [HCFA's] statements suggest that HCFA intends to read "learn" broadly…just how far HCFA may stretch the language…must await resolution in concrete cases. The regulation, however, seems to us not to go beyond the Secretary's statutory authority" *Health Insurance Association of America, Inc*, 23 F.3d at 421.

We appreciate the opportunity to submit these comments on the interim rule final rule. Please contact me if you have any questions.

Sincerely,

W. Bruce Shirk

cc: Ms. Tina Merritt, CMS

WBS:bct

CMS-6272-IFC-4

Submitter : **Date: 04/24/2006**

Organization : **American Pharmacists Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Sce attached.

CMS-6272-IFC-4-Attach-1.DOC

American Pharmacists Association
Improving medication use. Advancing patient care.
APhA

April 24, 2006

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-7272-IFC
PO Box 8017
Baltimore, MD 21244-8017

Re: CMS-6272-IFC

Dear Sir/Madam:

Thank you for the opportunity to comment on the interim final rule implementing amendments to the Medicare Secondary Payer (MSP) provisions of the Social Security Act. The American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, represents more than 57,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession. APhA, dedicated to helping all pharmacists improve medication use and advance patient care, is the first-established and largest association of pharmacists in the United States.

The interim final rule amends the Medicare Secondary Payer provisions to clarify that the Medicare program should be a secondary payer to the maximum extent possible. This clarification and the related technical amendments were mandated by the Medicare Modernization Act (MMA). APhA recognizes Congress' and the Centers for Medicare and Medicaid Services' (CMS) desire to ensure that the Medicare program does not unnecessarily pay for products or services that should be reimbursed by another payer. Positioning Medicare as the secondary payer when appropriate can save the Medicare program from unnecessary financial expenses *if* the amendments are implemented properly.

Provisions of This Interim Final Rule with Comment Period
According to the interim final rule, one of the amendments to the MSP provisions would clarify that a primary payer, or an entity that receives payment from a primary payer, would be responsible for reimbursing Medicare if the primary payer has primary payment responsibility. The new § 411.22 would read as follows:

> (a) A primary payer, and an entity that receives payment from a primary payer, must reimburse CMS for any payment if it is demonstrated that the primary payer has or had responsibility to make payment.

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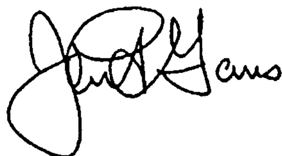
APhA understands the intent behind this provision – the Medicare program should be reimbursed if another payer had primary responsibility for covering a drug or service claim. However, APhA is concerned that the amendment directs the Agency to seek reimbursement from the primary payer, as well as an entity that receives payment from the primary payer. The amendment appears to allow CMS to seek payment from a health care provider such as a physician or pharmacist. And without clarifying language to the contrary, this section could be interpreted to allow Medicare to seek reimbursement from the provider first, before going to the primary payer.

APhA urges the Agency to pursue implementation of the MSP provisions through the payers, not the providers. The issue of whether Medicare or another payer has primary responsibility for a drug or service claim is a payment issue between the two payers, not the provider. CMS should pursue payment from the primary plan first. Seeking payment from the provider, rather than the payer, is inappropriate and may force providers to consider discontinuing providing services to Medicare beneficiaries.

In summary, APhA requests that the Agency further clarify the amendments to the MSP provisions in the final rule. We suggest the addition of language stating that Medicare will pursue reimbursement from the primary payer first; and that Medicare will not seek payment from providers that have not been paid by the primary payer for the claim in question.

Thank you for your consideration of the views of the nation's pharmacists. Please contact Susan K. Bishop, Director, Federal Regulatory Affairs at 202-429-7538 or SBishop@APhAnet.org, or Susan C. Winckler, Vice President, Policy and Communications at 202-429-7533 or SWinckler@APhAnet.org with any questions.

Sincerely,



John A. Gans, PharmD
Executive Vice President

cc: Susan C. Winckler, RPh, Esq, Vice President, Policy & Communications and Staff Counsel
Susan K. Bishop, MA, Director, Federal Regulatory Affairs

Submitter : **Dr. Michael Maves**

Date: 04/24/2006

Organization : **American Medical Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Sec attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

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