

What Physicians Should Know About the Medicare Modernization Act Part B Drug Reimbursement

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (“Modernization Act”) has received significant press for the prescription drug benefits that will be made available to Medicare beneficiaries in 2006. Medicare already covers a small number of drugs under Part B, and the Modernization Act also impacts physicians and how they are reimbursed when prescribing Medicare Part B drugs at the present time.

Medicare currently covers certain outpatient prescription drugs and biologicals under Medicare Part B, primarily physician-administered drugs. For over a decade, Medicare reimbursement for Part B drugs has been based on the average wholesale price (“AWP”), a term that has never been defined by statute or regulation. Although drug manufacturers do not set the price at which wholesalers actually sell drugs to retail customers, manufacturers have historically published an AWP for their drugs in industry publications such as the Red Book, Blue Book, and Medispan, which are then used by CMS (the Centers for Medicare & Medicaid Services) to determine the Medicare reimbursement. Consequently, physicians were able to acquire drugs at prices below (sometimes significantly below) the AWP, but nevertheless were able to be reimbursed at 95 percent of the AWP by Medicare. This gap between the provider’s cost for the drug and the reimbursement based on AWP, termed the “spread,” has led prosecutors to contend that drug manufacturers have inflated the AWP of their drugs in order to entice physicians to buy their products based on the profit to be made on the spread.

In response to these reports of purported abuses, Congress included significant changes to the AWP reimbursement methodology under the Modernization Act. Accordingly, reimbursement for Part B drugs will change considerably in a complex three-step process to be phased in over three years.

Phase I: For 2004, 85 Percent of AWP

For drugs administered in 2004, the AWP is still used as a barometer of reimbursement, although the reimbursement percentage drops from 95 percent to 85 percent for most Part B drugs furnished on or after January 1, 2004. The AWP will be calculated as of April 1, 2003, placing a retroactive freeze on the AWP amount.

Phase II: For 2005, 106 Percent of the Average Sales Price

As of 2005, covered drugs are reimbursed according to whether they are classified as multiple source drugs or single source drugs. Multiple source drugs are defined as those with two or more drug products determined to be therapeutically equivalent by the FDA (meaning drugs with generic substitutes). Single source drugs and biologicals are products that are not multiple source drugs and that are produced or distributed under a new drug application approved by the FDA.

Phase II eliminates the use of AWP as a method of determining Medicare Part B drug reimbursement. Instead, multiple source drugs will be reimbursed at 106 percent of the volume-weighted average of the average sales price (“ASP”) at which all manufacturers of the drug sold this product. The volume-weighted average of the ASP is calculated in three steps. First, each manufacturer’s ASP for a particular drug is multiplied by the number of units sold by the manufacturer. This equals the manufacturer’s total sales for the drug. Second, all manufacturers’ total sales for drugs in the same billing and payment code are added together to produce the total sales for the drug itself. Finally, the total drug sales figure is divided by the total number of units sold by all manufacturers of drugs within the same code. This produces the average sales price weighted by the volume of sales at various prices. Thus, each

INSIDE THIS ISSUE

What Physicians Should Know About the Medicare Modernization Act Part B Drug Reimbursement	pg. 1
Protecting Privacy and Encouraging Research	pg. 2
CMS May Recoup Medicare Overpayments from Bankrupt Providers	pg. 4

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provider is reimbursed the same amount for a multiple source drug regardless of the price charged by the manufacturer.

Single source drugs or biologicals are treated differently because there is generally only one manufacturer for the product. Thus, single source drugs and biologicals are reimbursed at the lesser of the manufacturer's ASP or the wholesale acquisition cost ("WAC"). The WAC is the manufacturer's most recent list price reported in wholesale price guides or other publications, excluding prompt pay and other discounts, rebates or reductions in price.

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The Modernization Act also includes a monitoring mechanism to ensure that the prices reported by manufacturers are accurate. These monitoring provisions require the Office of the Inspector General ("OIG") to conduct surveys to determine the widely available market prices ("WAMP") of Medicare Part B drugs. WAMP is defined as the price a prudent physician or supplier would pay for the product, including routine discounts, rebates and concessions. These findings are reported to CMS, which may disregard the ASP if it exceeds the WAMP or the average price paid to manufacturers by wholesalers for drugs distributed to retail pharmacies ("AMP") by an applicable threshold percentage. If CMS chooses to disregard the ASP, it may replace it with either the WAMP or 103 percent of AMP. In 2005, the applicable threshold percentage is five percent; however, CMS will specify the appli-

cable threshold percentage annually and thus it may be increased or decreased accordingly.

Phase III: For 2006, 106 Percent of the ASP or Competitive Bidding

Finally in 2006, as an alternative to purchasing drugs under the ASP methodology, the Modernization Act authorizes CMS to establish a competitive acquisition program. The program allows physicians to select annually an approved CMS contractor to deliver covered drugs to them. Under the competitive acquisition program, the contractor, rather than the physician, will submit claims for the purchase of drugs and collect co-pays or deductibles from the Medicare beneficiary after drug administration. Drug companies will compete to be selected by the contractor as the vendor of particular products. By using a contractor, physicians may be able to reduce their overhead and their liability by not taking title to the drugs and taking advantage of the price of the product obtained through the contractor.

While there is still much to be seen in the development of Medicare drug pricing, physicians should be aware that CMS has broad discretion to disregard manufacturers' ASP and to use WAMP when reimbursing for drugs. CMS also has discretion to carve out products from the comparative acquisition program system. Additionally, the Modernization Act provides that there is no administrative or judicial review of payment amount determinations for Part B Drugs.

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Protecting Privacy and Encouraging Research

Protecting privacy and encouraging research often seem to be conflicting goals. But, contrary to the views of many, HIPAA privacy regulations do not prevent healthcare researchers from doing their jobs. Rather, the regulations recognize the unique needs of researchers and apparently intend to encourage research within the context of the regulations.

"Privacy" under HIPAA means protection for individuals (patients or research subjects) from the use or

disclosure of their healthcare information, described in the HIPAA regulations as "protected health information" or "PHI." The Privacy Rule, however, only applies to "covered entities" – an important distinction since, in the research area, many individuals and entities involved in research are not covered entities. Therefore, even though some entities may handle PHI, they are not covered by HIPAA and do not have an obligation to comply with its regulations, unless they otherwise agree to do so.

In most research situations, the HIPAA-covered entity will be a healthcare provider that engages in certain types of electronic billing transactions. HIPAA also applies to workforce members of covered entities, so individual physician researchers or lab technicians who are health system employees are bound by HIPAA. Research sponsors, on the other hand, even drug or device companies, may not be covered entities. The same holds true for CROs (Clinical Research Organizations) or independent IRBs (Institutional Review Boards). Generally, a laboratory that is not providing a service or product that is part of the treatment of an individual's healthcare needs will not be a covered entity.

In general, three different methods permit access to PHI, each with its own procedural steps: (1) authorization; (2) de-identification; and (3) other limited exceptions that encourage research.

Authorization

Authorizations are by far the most common method of facilitating researchers' access to PHI. Individuals may authorize the use and disclosure of their PHI for research and, once the authorization is obtained, the researcher is free to use or disclose the information within the terms of the authorization.

Patients or human subjects involved in research are also required to sign an informed consent, that is, to provide written consent to participation in the research study after being fully informed of all pertinent aspects of what they are consenting to. This consent may be different from, or in addition to, the simple consent to treatment that a patient may sign upon admission to a hospital or when seeking outpatient or office services.

Thus, potentially three different forms may be involved: (1) a consent to treatment; (2) a consent to participation in research, which has many required elements under federal law; and (3) a HIPAA authorization in which the patient consents to the use and disclosure of healthcare information that could be used to identify him or her. These three different consents may all be combined in one document, or be treated separately.

It is important to note that authorizations are specific permissions by the individual to permit use or disclosure of PHI for a particular purpose. The authorization for research must pertain to a specific study or the

creation of a research repository or database; it must be in writing and signed by the individual; and the actual uses and disclosures must be described to the extent possible.

De-Identification

De-identification is helpful but can be unwieldy since HIPAA requires the elimination of 18 separate elements that could be used to identify the individual. HIPAA is, however, most encouraging of research when the entity cannot de-identify the information and it is difficult to obtain an authorization. There are four approaches in this instance that may apply: waiver, use of limited data sets, use of information preparatory to research, and research on decedents' information.

A waiver means that the barrier to using or disclosing PHI is removed, not by the individual patient or subject, but by a third party. This third party can either be the Institutional Review Board (IRB) supervising the research or a Privacy Board, a new entity authorized under HIPAA to perform some functions related to HIPAA that are similar to the role of the IRB.

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Limited Data Sets

In other cases, limited data sets can be useful in assisting researchers in obtaining much needed information. Under this provision, certain PHI can be disclosed for research purposes without authorization or waiver, such as city, state, zip code, dates or other numbers or codes that are technically PHI but are not direct identifiers (i.e., not Social Security numbers). The covered entity and researcher must enter into a Data Use Agreement that outlines the specific permitted uses and disclosures by the recipient and

provides assurances and agreements that will prevent further unauthorized use of the information.

Other Exceptions

HIPAA does provide for other exceptions that permit researchers to access PHI in order to prepare a research protocol or study. For instance, a researcher may be given access to PHI if the covered entity obtains a representation from the researcher that the PHI is needed solely to be reviewed in preparation for developing a research protocol, the information will be viewed on the premises of the covered entity and the information is necessary to plan the research.

Accounting

While HIPAA clearly is intended to support research efforts, its main purpose is to protect the privacy of individuals. Towards this end, HIPAA also requires that the researcher or user of the data have an accounting available that includes information about what PHI was disclosed, to whom it was disclosed, the reason for disclosure, and so on. If multiple disclosures

have been made to the same person or entity, the disclosure information can be grouped in a reasonable way. Where disclosures concern 50 or more individuals, which may happen in the course of a large clinical trial for example, the accounting request may be satisfied by providing the information about the study more generally, that is, by providing basic information that describes the protocol, the researcher's name and contact information, and the time period of the study.

Congress and regulatory agencies are attempting to balance the rights of patients to control the use of their identifiable health information with the need for medical progress to continue through human subject research. Because of the accommodation to research in HIPAA, there are many routes by which a desired research goal can be accomplished – without unduly jeopardizing the patient's privacy.

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CMS May Recoup Medicare Overpayments from Bankrupt Providers

Financially troubled healthcare providers will often owe significant liabilities to the Center for Medicare and Medicaid Services ("CMS") as a result of Medicare overpayments they may have received from CMS. CMS's efforts to collect these overpayments may cause a provider to take drastic action, such as seeking bankruptcy protection, to salvage its enterprise in the face of CMS's collection activities. Bankruptcy is often seen as a viable option because it imposes an automatic stay on collection efforts by creditors.

A growing body of case law, however, holds that the recovery of overpayments by CMS is in the nature of a recoupment action under federal bankruptcy law and therefore not subject to the automatic stay provisions of the U.S. Bankruptcy Code. Under the Bankruptcy Code, when reciprocal obligations arise from the same transaction, a creditor may recoup the amount owed to it from the amount that it owes to the debtor. Thus, a provider that has received overpayments from CMS that is considering bankruptcy to, among other things,

forestall CMS's collection of the overpayments, should be aware that the Bankruptcy Code may be of limited use in preventing CMS's collection efforts.

In *Holyoke Nursing Home, Inc. v. Health Care Financing Administration (In re Holyoke Nursing Home, Inc.)*, 273 B.R. 305 (Bankr. D. Mass. 2002), the nursing home attempted to recover from HCFA (now CMS) approximately \$100,000 due to the nursing home but withheld by HCFA prior to the filing of the nursing home's bankruptcy petition and approximately \$78,000 withheld by HCFA after the petition date. The nursing home argued that the withheld payments were offsets, occurring within the 90-day preference period prior to the filing of the chapter 11 bankruptcy petition. As such, it argued that the offsets constituted avoidable preferential transfers under the Bankruptcy Code. The nursing home also contended that HCFA violated the automatic stay provisions of the Bankruptcy Code by withholding payments due the nursing home after the petition date. In response, HCFA argued that the withheld payments

did not constitute preferential transfers because such recoveries were in the nature of recoupment, rather than offset, and disputed the nursing home's allegations that it violated the automatic stay. While admitting that the "question is close," the bankruptcy court held that HCFA's actions were in the nature of recoupment and did not violate the automatic stay.

The bankruptcy court's decision was subsequently reviewed by a federal district court that considered two different approaches to analyzing the issue. One approach holds that the government's withholding of Medicare payments does not constitute a recoupment when the government withholds payments due in the current year in order to recoup payments overpaid in a different year. Thus such withholding violates the automatic stay if done without first obtaining relief from the stay. The other approach is that this withholding does constitute a recoupment by the government and is permissible without obtaining relief from the automatic stay, even when the funds withheld and the funds overpaid relate to different calendar years.

In a decision rendered in 2003, the appellate court concluded that the Medicare statute shows congressional intent that there should be an ongoing process, between HCFA and a provider, to adjust the compensation paid to the provider to account for Medicare overpayments or underpayments. Consequently, the court determined that such a process, even when it occurs across different calendar years and is subject to annual audit, should be seen as meeting the "same transaction" test for recoupment purposes. Consequently, the court found that "HCFA's withholding of amounts due to Holyoke post-petition, in order to recover pre-petition overpayments, is in the nature of a recoupment, and does not violate the automatic stay provision under 11 U.S.C. § 362(a)."

The issue of a government's right of setoff was also examined in the case of *In re Slater Health Ctr., Inc.*, a district court case from Rhode Island decided in 2004. In *Slater*, the nursing home had a Medicare Provider Agreement with CMS. After the nursing home filed a chapter 11 bankruptcy petition, Medicare gave the nursing home notice that audit results for 1997 and 1998 indicated that Medicare had overpaid the nursing home \$370,569 for those years. Medicare then offset the \$370,569 against amounts owed to the nursing home for post-petition services. In an effort to force Medicare to pay the \$370,569 to its estate, the nursing home contended that this amount did not represent an

"overpayment in the true sense of the word" and Medicare's offset of this amount against amounts due for postpetition services violated the automatic stay provisions of the Bankruptcy Code.

The district court in *Slater* noted that, consistent with the decision of the appellate court with respect to *Holyoke Nursing*, the "better reasoned approach" with respect to Medicare overpayments is that the recovery of overpaid funds through recoupment does not violate the automatic stay provisions of the Bankruptcy Code. Additionally, the district court disagreed with the bankruptcy court's ruling that equitable principles prevented Medicare from recouping the \$370,569 payment made to the nursing home. The district court noted that the determination of whether a Medicare overpayment may be recouped from amounts owed by Medicare to a provider is a matter of Medicare law and further found that "because the Medicare statute expressly provides for adjusting the amount owed to a provider by withholding past overpayments," the amount in dispute, \$370,569, was not actually owed to the nursing home. Therefore, there was no balance owing to the nursing home that could be made available for distribution to the nursing home.

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The *Holyoke Nursing* and *Slater* cases indicate that courts will likely give deference to CMS's power to recoup overpayments under the Medicare statute and will allow CMS to reclaim these funds from providers in bankruptcy without first obtaining relief from the automatic stay. In light of these decisions, a provider with overpayment liabilities to CMS should be aware that bankruptcy proceedings may be of limited usefulness in preventing CMS from collecting overpayments made to the provider under the Medicare statute.

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