

Health Law

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Medicare Prescription Drug, Improvement and Modernization Act of 2003 and Its Impact on Physicians

Executive Summary

Although the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("2003 Act") is receiving extensive publicity for the new Medicare outpatient drug benefit, physicians should be aware of increased revenue opportunities and modernization of the Medicare Program that impact them directly.

The 2003 Act assists physicians in three important areas. First, physicians will be ensured increased payment for their services. Second, coverage of physician services will be expanded through new preventive screening benefits and relaxed reassignment rules. Third, claims processing methods will be reformed to remove administrative burdens that deny payment unnecessarily.

The 2003 Act also provides relief to other Medicare suppliers, such as Independent Diagnostic Testing Facilities ("IDTFs"), that are paid under the Part B physician fee schedule.

GCD's Health Law Department analyzed the impact of the 2003 Act on essentially all industry players including hospitals, PBMs and pharmaceutical companies, rural hospitals, skilled nursing facilities, durable medical equipment suppliers, and employers. Please visit our website (www.gcd.com) at <http://www.gcd.com/seminars/publist.asp?groupid=3> to obtain any of the above detailed guidance which may be of interest to your organization.

Payment Increase

The conversion factor for the physician fee schedule will increase by 1.5% for calendar years 2004 and 2005. The conversion factor is the dollar amount that, when multiplied with the relative value units ("RVUs") for a particular service, yields the Medicare payment amount for that service. This means that for 2004, the 4.5% decrease set to take effect under current law will be replaced by a 1.5% increase (a total increase of 6%), and the conversion factor will increase from \$36.7856 in 2003 to

approximately \$37.3374 in 2004 and approximately \$37.8975 in 2005.

Coverage of New Preventive Services

Physicians and other Medicare practitioners (*i.e.*, nurse practitioners, clinical nurse practitioners, physician assistants, and certified nurse midwives) may be reimbursed for initial routine physicals furnished to beneficiaries who become eligible for Medicare Part B on or after January 1, 2005, provided that the physical is furnished within the first six months of the beneficiary's eligibility. The physical includes: (1) measurement of height, weight, and blood pressure; (2) one electrocardiogram; and (3) patient education, counseling, and referrals for other screening and preventive services covered by Medicare to promote health and detect disease. This new benefit does not cover clinical laboratory tests, which are paid separately.

In addition, effective January 1, 2005, Medicare will cover cardiovascular screening blood tests that measure cholesterol levels and other lipid or triglyceride levels or other indications of cardiovascular disease as approved by the Secretary. Beneficiaries may not be tested more than once every two years.

Also beginning January 1, 2005, Medicare will pay for diabetes screening tests, such as fasting plasma glucose tests or other tests approved by the Secretary. Physicians may perform these tests on beneficiaries who possess certain risk factors, such as hypertension, dyslipidemia, and obesity, or a family history of diabetes. Beneficiaries may not be tested more than twice in one year.

Enrollment of Staffing Companies

Medicare makes payment only to the Medicare practitioner or other Part B supplier that furnishes a covered service unless there is a permissible reassignment. Reassignment to a clinic is permissible, for example, if the physician is an employee of the clinic or the physician is an independent contractor and the physician performs all

services within the four walls of the clinic. Even though staffing companies may hire physicians (or other Medicare practitioners) as employees or independent contractors, they cannot receive Medicare payment directly from the Part B carrier because they may not enroll in the Medicare Program as providers or suppliers.

The new law permits staffing companies to enroll in Medicare, bill Medicare, and receive payment. This means that an independent contractor physician may reassign to the staffing company even though he or she does not perform any services on the premises of the staffing company and, instead, is leased out to a clinic by the staffing company. This provision may lead to the elimination of the so-called “clinic exception” in which the independent contractor physician is required to perform all services within the four walls of the clinic.

Advanced Beneficiary Notice (“ABN”)

The Secretary is required to establish a process whereby physicians can determine whether Medicare would cover certain services before rendering such services. The Medicare contractor must render a decision within 45 days. The physician or the beneficiary has the right to request a redetermination if the contractor should deny payment in advance, but these advance determinations (or redeterminations) are not subject to additional review. The beneficiary retains all rights to the usual administrative or judicial review process after receiving the service or receiving a determination that a service would not be covered. More importantly, the prior determinations would be binding on the contractors.

Although this provision sunsets after five years, the Secretary is required to establish the new process shortly so that it addresses physician requests that are filed within 18 months after enactment. Overall, this new pre-determination process should give both physicians and patients more control and flexibility by eliminating the financial uncertainty about payment.

Documentation of Office Visits

The Secretary is required to amend the documentation guidelines (“DGs”) for evaluation and management (“E&M”) services to reduce paperwork burdens on physicians. In particular, any revisions to the E&M DGs must meet the following objectives:

- (1) identify clinically pertinent documentation required to code accurately and assess coding levels accurately;

- (2) decrease the level of non-clinically pertinent and burdensome documentation time and content in the medical record;
- (3) increase accuracy of reviewers; and
- (4) educate physicians and reviewers.

In order for the Secretary to establish new or revised E&M DGs, the Secretary first must: (1) develop the DGs in collaboration with and using input from practicing physicians of various specialties in a teaching and nonteaching setting; (2) establish a plan with specific goals and a set schedule; (3) conduct pilot programs to test the DGs; (4) determine that the DGs have met the set goals; and (5) establish and implement an education and training program. Furthermore, the Secretary must submit a report to Congress within six months after the pilot studies are completed. Therefore, this affords great opportunities for physicians of all specialties to voice their concerns over the current E&M DGs.

Changes to Historical Medicare Part B

Under the 2003 Act, most drugs historically covered by Medicare Part B (*i.e.*, those administered by physicians) will be paid at 85% of average wholesale price (“AWP”) through December 31, 2004. Beginning in 2005, however, drugs and biologicals, other than pneumonia, flu and hepatitis B vaccines and those associated with certain dialysis services, blood or blood products or radiopharmaceuticals, will be paid using either an *average sales price (“ASP”) methodology* or, in the case of a physician who elects to participate, through the *competitive acquisition program*.

Average Sales Price Method. Medicare’s payment to physicians under the ASP methodology will equal 106% of ASP. This may result in lower reimbursement to physicians who historically were able to purchase drugs at a cost lower than the manufacturer-reported AWP and then obtain reimbursement based on AWP. While the 2003 Act increases practice expenses as well as RVUs used to calculate the physician fee schedule to cover the costs of drug administration, there still may be a net loss in reimbursement to physicians.

Competitive Acquisition Program Method. As an alternative to purchasing drugs under the ASP methodology, the 2003 Act requires the Secretary of the Department of Health and Human Services (“HHS”) to establish a competitive acquisition program (“CAP”) for competitively biddable drugs and biologicals. Under the CAP methodology, physicians may select a contractor on an annual basis who would deliver covered drugs to the physician. By using a contractor, physicians should be

able to reduce inventory and administrative costs and, as the physicians do not take title to the drugs, their liability should be reduced. Under CAP, the supplier, rather than the physician, will submit claims for purchased drugs and collect co-pays or deductibles from the Medicare beneficiary after drug administration. The competitive acquisition program will be phased in beginning in 2006.

Modifications to Carrier Practices That Impact Physicians

Buried within this massive legislation are certain mandated carrier education efforts and limitations on their audit abilities that directly impact physicians.

- No “Penalties” If Suppliers Bill Based on Contractor Guidance. With respect to written or email guidance from the Centers for Medicare and Medicaid Services (“CMS”) or a carrier on or after July 24, 2003, physicians will not be subject to “penalties or interest” for furnishing or billing for services based on this guidance, even if the guidance was wrong. This suggests that a physician will not be subject to recoupment of overpayments when relying on CMS guidance. The language, however, is a bit ambiguous and could be interpreted to allow for recoupment, but no interest or other penalties.
- Stepped-up Supplier Education. CMS and its carriers have received additional funding and mandates with regard to increased supplier education and outreach activities.
 - As of October 1, 2004, contractors are required to respond to written inquiries within 45 days of receipt of the inquiry.
 - Contractors are also forbidden to use a record of attendance (or non-attendance) at these educational activities to select or track providers for audit.
- Limitations on Prepayment Audits. Contractors often request records and documentation from physicians when there is no evidence to suggest that any claim is in error. This is referred to as a “random prepayment review.” Effective one year after enactment, carriers may only conduct random prepayment reviews to assist them in developing contractor wide claims payment error rates or under other circumstances that will be set forth in regulations. In other words, carriers will not be permitted to randomly ask for documentation in a fishing expedition to identify erroneous claims and recoup overpayments. This presumably will be a compliance measure in carriers’ contracts with CMS.

- Limitations on Focused Audits After a Disclosure. If a physician or group practice identifies an improper billing practice to the carrier, that carrier is prohibited from initiating a non-random (or focused) prepayment review of that physician or group unless there is a “likelihood of sustained or high level of payment error.”
- Regulations Must Be Published Within Three Years. CMS is required to issue final regulations within three years of issuing a proposed rule, absent exigent circumstances. Although this may not sound like a rigorous standard, it’s worth noting that despite the January 9, 1998 proposed Stark regulations, to date there are still no regulations finalizing most of the compensation exceptions.

Drug Benefit

The 2003 Act added a new Medicare drug benefit (Part D), offered by drug plans or Medicare Advantage plans. This benefit covers outpatient prescription drugs not previously covered by Medicare. It requires payment of an additional premium (the Part D premium) by the beneficiary, although the premium is subsidized by the federal government. Congress authorized \$400 billion over a 10-year period to subsidize premiums. The benefit will not be available until 2006. In the meantime, HHS will review and endorse drug discount card programs that meet certain criteria. Both the discount card and Part D drug plan coverage provide for additional subsidies for eligible low-income individuals. It is hoped that the availability of some drug coverage will enhance the health status of Medicare beneficiaries and avoid costly hospital visits. Of particular interest is a provision requiring development of a safe harbor from Stark and the anti-kickback laws in order to allow drug plans to provide non-monetary items (such as software) to physicians in order to support their use of and development of the electronic prescription program. Government grants to physicians are also available for this program. Physicians will also have the ability to prescribe non-formulary drugs for their patients under certain circumstances. For more information on the drug benefit, please review the managed care guidance that is available on our website.

Managed Care – Medicare Advantage

In order to revitalize the Medicare managed care program, currently called Medicare+Choice, Congress has made significant changes to the program. In addition to changing its name to “Medicare Advantage,” the 2003 Act immediately increases payments to most plans in 2004. Further, beginning in 2006 the new law provides for payments based on bids from the plans and adds a new

regional plan choice that will cover geographic service areas that are significantly larger than the service areas covered by current Medicare+Choice plans. Because the regional plans are intended to cover rural areas previously underserved by the Medicare+Choice program, Congress has provided additional financial support to regional plans, including incentives and risk limitations. There are also financial incentives available for provider network development. Finally, in 2010, a controversial demonstration project will begin. This project will pit the traditional fee-for-service program against Medicare Advantage plans. For more information on these changes, please review our managed care guidance that is available on our website.

Employer-Related Provisions

There are two important developments in the 2003 Act for physicians in their role as employers that sponsor health benefit plans for their employees and retirees. Beginning January 1, 2004, employers will be able to use tax-favored trust accounts – health savings accounts (“HSAs”) – that offer an opportunity for employees to contribute money on a pretax basis and use amounts accumulated over the years to pay for medical expenses or even retiree medical coverage. Also, beginning in 2006, special subsidies will be offered to the sponsors of retiree medical plans that continue to provide prescription drug coverage at certain levels to retirees who are eligible for the new Part D prescription drug benefit.

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For more information on what the new Medicare law means, please contact the GCD attorney who serves as your regular contact. Alternatively, please contact any member of our Health Law Department.

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