Medicare Challenges and Solutions—Reimbursement Issues in Treating the Patient With Colorectal Cancer

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ABSTRACT

BACKGROUND: Medicare covers costs far more than 50% of all cancer patients, and most private payers follow Medicare's lead on coverage and benefits for cancer care. Medicare and private payers are legally required by federal statute to cover anticancer chemotherapeutic products based on U.S. Food and Drug Administration-approved labeling and indicate how off-label uses are covered.

OBJECTIVE: To review reimbursement issues unique to Medicare with regard to oncology drugs.

SUMMARY: Currently, the Centers for Medicare & Medicaid Services (CMS) recognizes 2 compendia for purposes of evaluating off-label uses of drugs. Coverage determinations can be pursued nationally, locally, and case by case. Because of the impact and scope of colorectal cancer on the national budget, CMS initiated a process to establish national coverage determinations. This and other such Medicare reforms will have significant repercussions for clinicians who work with oncology patients. Major administrative and access challenges for both health care providers and beneficiaries include a diverse array of plan choices. In terms of Medicare Part D, the 25% of patients who are chronically ill and prescribed expensive therapies (including antineoplastics and supportive care agents) may find the coverage gap ("donut hole") challenging and even prohibitive in their access to appropriate care. Lack of coverage could potentially affect therapy compliance, and managed care must pursue additional payment or coverage support mechanisms. Evaluating formularies will be critical for cancer patients and those who use specialty drugs as they select their Part D plans in the future.

CONCLUSION: Oncologists and their patients are left with difficult choices regarding not only the clinical efficacy of a treatment but also the financial considerations of the treatment.

KEYWORDS: Cancer therapies, Coverage gap, Medicare coverage, Medicare Part D, Medicare reform, Off-label prescribing

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Medicare's impact on managed care and the private market has dramatically increased as more payers offer coverage and care for Medicare beneficiaries through Medicare Part D. This growing influence has created new processes, prompting a push-and-pull interplay between public and private policies that is unlikely to resolve in the near future. The direct effects of public and private policies and practices appear to have reciprocal effects, more so today than in the past. This article will examine traditional Medicare coverage of cancer therapies, Medicare reform, Medicare Part D, and the implications of all of these for providers and cancer patients, with an emphasis on the differences in public and private approaches. Specific examples used will relate to colorectal cancer (CRC).

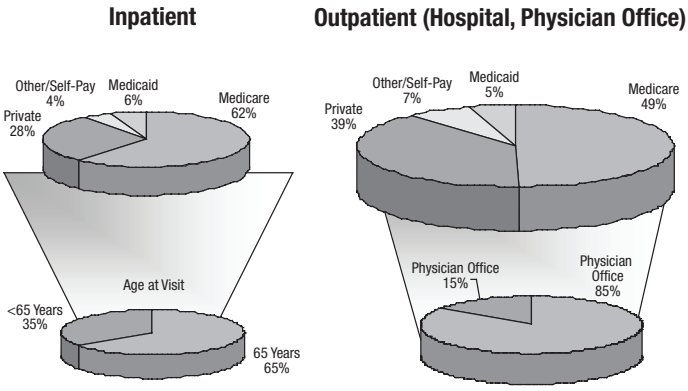
Previous articles have discussed infusion therapies and the brighter, more promising horizon for oral antineoplastics. Although the field of oncology will continue to rely on and welcome new infusion products, oncology practitioners are looking forward to the numerous oral products in the research pipeline. Managing existing and soon-to-be approved oral antineoplastics will create financial, administrative, and utilization management challenges in general, especially within the context of Medicare Part D.

The Burden of Colorectal Cancer

Medicare's need to address CRC is largely based on the volume of patients affected; CRC is the second leading cause of cancer death in the United States. Because this disease generally affects people aged 50 years or older and the mean age at diagnosis is 72 years, most affected Americans are Medicare-eligible.[1] As the "baby boomers" age, the number of and burden associated with Medicare-insured CRC patients will continue to rise. Hence, Medicare has been diligently working to establish a way to manage CRC appropriately, not only clinically but also financially, so that all beneficiaries have appropriate access to the improving standard of care. Medicare provides coverage for more than 50% of all cancer patients, and many private payers follow, or borrow significantly from, Medicare's policies for coverage of and payment for cancer care.

Currently, Medicare is a significant payer for CRC (see Figure). It pays for 62% of costs associated with inpatient CRC care and 49% of all outpatient CRC care, of which 15% is provided in hospital outpatient departments and 85% in physician's offices. Medicare's typical beneficiary with CRC can be expected to be among the oldest and sickest of CRC patients.[2] Discussion of Medicare in any context is often facilitated if the "parts" (e.g., the "entitled" Part A and the optional Parts B, C, and now D) are explained. Table 1 describes Medicare coverage.

FIGURE Who Are the Major Payers for Colorectal Cancer?



Source: Lash Group analysis of the following data sources:
Inpatient: 2003 HCUP nationwide inpatient sample.
Outpatient: weighted average of 1997-2003 National Hospital Ambulatory Medical Care Survey data and National Ambulatory Medical Care Survey data.
Age at visit: 2003 HCUP nationwide inpatient sample.

TABLE 1 Medicare Benefit Categories

PART A	PART B (Optional)	PART C (Optional)	PART D (Optional)
• Hospital inpatient • Skilled nursing facility care • Home health • Hospice	• Physician office • Hospital outpatient • Community mental health centers	• Medicare Advantage (Medicare managed care) • Available with or without PDP	• New PDP benefit • Started 1/1/2006

PDP = prescription drug plan.

In most cases, Medicare beneficiaries receive Part A coverage on a premium-free basis. Parts B, C, and D supplement Part A coverage and are optional benefits requiring separate premiums. Medicare's regulations covering cancer are statute-based; if medically reasonable and necessary, Medicare must provide reimbursement for anticancer agents based on the agents' U.S. Food and Drug Administration (FDA)-approved labeling.[3] Statutory language in Section 1861(t)(1) and (2) of the Social Security Act provides Medicare reimbursement for off-label indications of products in chemotherapeutic regimens as well, and for off-label prescribing, a practice that is frequently used in the oncology field. The provisions are straightforward: the off-label use must be supported by 1 or more of the compendia listed in the statute, which are discussed further below, or the carrier involved must determine that the treatment is medically accepted based on peer-reviewed supportive clinical evidence appearing in publications as identified by the Secretary of the U.S. Department of Health and Human Services (HHS). Compendia are critical for applying Medicare's off-label coverage policy because of how the statutory language defines its use. The importance of the compendia also extends to the private insurance industry. However, with significant variation among and within private payers, the private market does not use compendia in the consistent manner that Medicare does. Some private payers use compendia listings along with their own pharmacy and therapeutics reviews, which often include primary literature reviews, clinical data, and primary information from drug manufacturers.[3,4]

Thus, to understand coverage policies for Medicare beneficiaries, health care providers often reference compendia listings or locate literature that supports the cancer diagnosis they are treating. The current Medicare-approved compendia include the United States Pharmacopeia Drug Information (USP-DI) and the American Hospital Formulary Service Drug Information (AHFS-DI). Medicare carriers generally use both compendia in their coverage decision-making processes and to confirm information found in each. It is important to note that a negative listing in one of the recognized compendia will trump a positive listing in another and potentially result in noncoverage.[4]

In addition to the USP-DI and AHFS-DI, other compendia are petitioning to be included in Medicare's list of approved compendia. One, the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, is becoming increasingly important. A nationally recognized group, NCCN is actively involved in creating and disseminating evidence-based and consensus guidelines for cancer care. This compendium delineates uses of drugs and biologics in the care of cancer patients, listing FDA-approved disease indications and specific NCCN recommendations for use as well as defining levels of evidence and categories of consensus-supporting recommendations. Other drug reference sources, including DRUGDEX System, the compendium used by Medicaid agencies, and *Facts & Comparisons* and *Clinical Pharmacology*, are also seeking formal recognition and CMS approval as part of the compendia process within the coverage determination.

Pathways to Coverage

CMS determines coverage for anticancer agents using 1 of 2 pathways: they make national doverage determinations (NCDs) or local coverage determinations (LCDs) through local CMS contractors. CMS will often use the NCD pathway if a technology, drug or biologic, device, or other medical entity is or will be a significant burden on the Medicare program. Factors like high patient volume or significant cost may influence a decision to develop an NCD to outline coverage provisions. CMS will also consider developing NCDs if treatment associated with a technology, drug, or device varies widely. In the case of CRC, clinicians and patients have the choice of numerous treatment options and therapeutic alternatives, and additional therapies are in premarketing stages of testing. Considering these reasons as well as the current and expected future burden of CRC on the Medicare system, it becomes clearer why Medicare elected to embark on

the NCD pathway for the management of CRC. This is discussed in detail below.

The second pathway to coverage, the LCD, is through local contractors who often subsequently post their decisions, which are based on either FDA-approved indications or the off-label rules described previously. Local contractors publicly post LCDs and coverage bulletins to their Web sites for providers and patients to reference and understand coverage policies determined using this method. References based on previously reviewed requests for coverage are also used systematically to make case-by-case coverage determinations.

A History Lesson: CRC and CMS

The NCD process is quite involved and time-consuming; it takes months to years to complete, but the focus is to methodically evaluate evidence that will be used to develop consistent coverage policies for health technologies. Obvious and long-standing concern about CRC prompted CMS to open an NCD review process for oxaliplatin in February 2003. This was allowed under CMS's authority to provide provisional coverage for products and therapies using the coverage with evidence determination (CED) protocol (which is discussed more thoroughly below). As additional medications became available to treat CRC, CMS expanded the scope of their NCD development efforts into the entirety of CRC rather than into 1 drug alone, and specifically into off-label uses of particular drugs within the CRC arena. They included irinotecan in the ongoing process in May 2003 and the biologics bevacizumab and cetuximab in September 2004.[5]

The FDA's "Fast Track" designation process also addresses certain oncology products when the combination of a product and a claim reveal an unmet medical need. The FDA process also allows agents to undergo "Priority Review"—reducing the expected review time from 10 months to about 6 months—or "Accelerated Approval"—when a promising product is intended for life-threatening diseases. Hence, these products become available commercially on the basis of preliminary evidence prior to formal demonstration of patient benefit.[6]

Note that the FDA bases its decisions on safety and efficacy in product claims. CMS then accepts the FDA decisions to approve products before allowing them to come to market. However, CMS's approval does not address its responsibility to provide coverage policies intended to ensure that products are used based on "reasonable and necessary" criteria. These are related yet different missions that the FDA and CMS own. CMS has a responsibility to provide beneficiaries access to the newest products and therapies, but it also has the responsibility of ensuring that adequate evidence exists to designate these therapies as "reasonable and necessary" within the conditions for treatment. At times, based on the speed of market approval and the populations in which products may have been tested as part of the FDA approval process, such evidence may be lacking (e.g., if agents navigate an expedited review process at the FDA).

As part of the NCD development process, and for the first time regarding drug therapy, CMS formally instituted and began providing coverage for products used in off-label situations while it evaluated clinical evidence; beneficiaries were granted coverage only if they were involved in clinical trials sanctioned by CMS. By doing so, clinical evidence was systematically and consistently collected and used to develop the NCD over time.

This process is a CED plan.[7] CMS had applied CED plans previously; in all cases, the process made headline news. The first examined lung volume reduction surgery in patients with severe emphysema. The agency sought evidence to identify patients who would truly benefit from these surgeries. Others addressed the use of positron emission tomography scans for Alzheimer's disease; bariatric surgery for patients older than 65 years; and expanding coverage of implantable cardioverter defibrillators. When Medicare uses the CED process to make coverage decisions, it is a burden in and of itself. Some concerns include the costs of the process, the provision of trial medication data collection activities and analyses, and potential ethical repercussions of requiring participation in this clinical evidence collection process for coverage. These issues have and will continue to be discussed in public forums.

For CRC, the CED and NCD processes allowed for a large number of therapeutic options, and the milieu has been changing very quickly as more options continue to become available. In January 2005, after almost 2 years, CMS produced its NCD for off-label uses of CRC therapies. The NCD process is lengthy and, as in many diseases, the options for treating CRC are changing so quickly that taking 2 years for these review processes may be too slow. CMS and policy makers will continue to evaluate the need and utility of these processes, balancing them with the resources required.

The Changing Face of Medicare Part B

What has patient experience been as drug costs continue to rise? This is a question that has weighed heavily on all stakeholders' minds over the last few years, and especially since Part D implementation. Patients have encountered some very difficult issues, and the market has responded in different ways.

In the United States, the issue of drug costs has recently taken on more policy significance. In 2006, CMS introduced the concept of basing provider-administered product reimbursement on average sales price (ASP). Until then, average wholesale price (AWP) was most commonly used to determine provider reimbursement for provider-administered products. CMS's goal was to create a market-based approach to reimbursement with the presumption that this would decrease Medicare program spending. Specifically, the ASP-based formula has accomplished this. However, significant administrative issues still exist for providers. Are bona fide service fees included in ASP calculations? How is ASP calculated for newly approved medications? How should medications bundled together in contracts be

addressed? Clearly, further clarification about ASP calculations is necessary. These issues are crucial for providers since medication-based reimbursement is still a large part of their overall patient care equation. (See Update section.)

Many providers and provider groups have also reported that new administrative codes were not updated or adjusted in 2006. The resulting confusion led to inconsistent use of codes throughout 2006. Providers report that the Medicare claims payment process has been fraught with problems, and many carriers do not yet have the proper codes and payment rates loaded into their databases appropriately, even for 2006. These issues translate into problems for providers—payment cuts for drug product administration pursuant to ASP use and inaccurate claims payments for professional services. Clinicians and lobbyists continue to express concern, in many cases to Congress, that the cuts proposed for 2007 will further damage care coordination and complicate both patient care and office management issues that continue to place financial pressure on providers. (See Update section)

Their concern is valid. CMS announced changes proposed for 2007 in August 2006, and the comment period ended in October 2006. Many stakeholders have rallied against the proposed 5.1% reduction in the physician fee schedule; it is larger than predicted, and arguments have been made that it is inappropriate. Providers claim that this reduction will severely affect their ability to provide quality care to their patients. Additionally, CMS's 1-year oncology demonstration project (a program to gather specific information relevant to cancer patients' quality of care, including their treatments, the spectrum of care they receive from their doctors, and whether the care represents best practices) expires at the end of 2006. This could cost providers an additional $150 million in the reductions realized in 2006. The demonstration project helped minimize some of those financial effects of lower physician-office reimbursement for services, and provided incremental payment for medications and their administration to patients. What will follow, and the effects patients will experience, are now uncertain. (See Update section)

The issue of beneficiary out-of-pocket costs continues to be important—more so as patient out-of-pocket responsibilities increase. As prices for drugs increases, patient premiums, deductibles, and copayments also rise. For physician-office-based care, Medicare pays 80% of its allowable fee for office visits and medications administered by providers, leaving the remaining 20%, and the annual deductible, as the beneficiary's responsibility. To illustrate how a 20% copayment can be burdensome for patients, consider an example of 1 CRC treatment: bevacizumab (340 mg) and 2 hours of infusion will cost the patient $497.49, plus their $124 annual Part B deductible and $88.50 monthly Part B premium. Note that the annual Part B premium becomes income-indexed in 2007.[8] Medicare pays $1,989.95 for the medication dose and administrative fee for giving the treatment. As these Part B-covered products are approved and reach the market with unprecedented price tags, intense scrutiny of Medicare benefits and medical costs will surely follow. The health care industry and the marketplace are now dealing with the burden of finding ways to ensure that out-of-pocket responsibility is not a barrier to health care access. (See Update section)

Medicare Part D

The basics of Part D are familiar to most managed care pharmacists by now. Beneficiaries have a diverse array of prescription drug plan (PDP) sponsors and Medicare-Advantage prescription drug (MA-PD) plan sponsors from which to choose. The available MA-PD plans offered in 2006 neared 1,900. As of June 2006, the HHS reported that 22.5 million beneficiaries had enrolled in Medicare Part D. Many chronically ill beneficiaries reach the "donut hole" during the third quarter of the year and thus will likely bear the full brunt of the coverage gap responsibility. (For all patients, Medicare covers 75% of the first $2,250 worth of drugs, but after that, coverage drops to zero and only resumes when the beneficiary reaches $5,100 in out-of-pocket expenses. Then, for most patients, Medicare pays 95% of costs. The approximately $3,000 gap in which patients must pay the entirety of drug costs is called the donut hole.) Because chronically ill patients typically have a profile that includes many medications, it is important to consider not only individual medications and their associated costs but also all medications and their collective costs in the donut hole conundrum. The vast majority of PDPs are not offering coverage through the donut hole in 2006. Individual plans' sponsors have considerable latitude in this matter, however, and some plans do offer coverage. CMS data suggest that only 2% of plans cover branded and generic products and 13% cover only generic drugs through the donut hole.

The 2006 average monthly premium for beneficiaries enrolled in Part D was about $37, and it is likely to be slightly lower in 2007. Although experts expected that most plans would require a standard deductible of $250, only 34% of plans actually did. Many plans (58%) have no deductible. Note that this was quite different from what CMS provided as the model structure, knowing that individual plan sponsors had the autonomy to develop and provide plan designs that were actuarially equivalent to the standard structure.[9]

Specialty drugs deserve separate discussion, especially since many antineoplastics are considered specialty drugs. Most formularies have, until now, included specialty drugs and expensive therapies in the higher (third and fourth) tiers. That trend continued in Part D formularies, wherein more than 90% of plans have tiered structures and approximately 6% of drugs fall into the fourth tier. Much to the surprise of many, some Part D formularies specifically listed medications that are Part B-eligible. Medicare is in the process of issuing guidance for 2007, and it will include specific language concerning specialty products (e.g., products that have negotiated prices exceeding $500 per

month will be placed in a specialty tier and be covered with a coinsurance of 25% or less). This is the first time that CMS's involvement has reached the level of telling plan sponsors how they must manage those products. Cancer patients will need to evaluate formularies very carefully as they select their 2007 Part D plan.

Many experts attempted to estimate how many beneficiaries would hit or surpass the donut hole in 2006. Medicare designed the donut hole as a risk management tool, so beneficiaries would share responsibility in their overall medication management costs. The Kaiser Family Foundation originally estimated in 2004 that 24% of beneficiaries would experience out-of-pocket spending within the donut hole. Recent figures, however, indicate that 35% of Medicare beneficiaries reached the donut hole by August 2006 and that of those, 16% would discontinue treatment all together.[10] Patients who are on relatively inexpensive maintenance medications may not be as likely to feel the dramatic effects of this out-of-pocket responsibility, but those taking more expensive therapies such as oral cancer products are likely to reach the donut hole more quickly, some even as early as February.

Currently, as exceptions to Medicare law, Medicare Part B covers select oral antineoplastics, because they are considered prodrugs. For example, the fluorouracil precursor capecitabine is one of these Medicare Part B-covered drugs. Other products frequently used in the cancer population are provider-administered (e.g., injectables, infusables) and are Part B-covered, both as antineoplastics and supportive care products such as hemopoetic agents, antiemetic products, and some antinausea agents. It is important to note that cancer patients often have an armamentarium of other medications used in their overall cancer management plans, such as oral or self-administered therapies used for pain management and mental health. These agents play a significant role in the care of cancer patients, and they are not covered under Part B, but rather Part D.

In a 2004 editorial in the *New England Journal of Medicine*, Deborah Schrag, MD, summarized some of the cost concerns specifically related to CRC.[11] She traced the progress of chemotherapeutic agents from the 1960s, when fluorouracil was the primary chemotherapeutic agent available to treat CRC, to the 1990s, when the FDA began to approve what was then 5 new agents (irinotecan, oxaliplatin, capecitabine, bevacizumab, and cetuximab) for this indication. These therapies improved survival from a mean of 8 months without treatment to 12 months with flourouracil. After 2002, median survival increased to 21 months with use of the newer agents, and lengthier survivals are expected as data from ongoing trials is collected. Doubling the median survival increased the cost of therapy 340 times, based on AWP—a staggering figure. Note that this figure does not account for the increased cost of simply living longer and being able to receive more cycles of therapy; it is based on an 8-week treatment plan. The cost of managing metastases and subsequent tumors is also not considered in this editorial comment. This is a very real example of how costs of care for CRC are increasing at rates that are significant and especially meaningful for patients as they are sharing the financial burden of receiving this care and, at times, with benefits that are being publicly debated.

As prices continue to rise, and life expectancy increases, Medicare CRC patients who lack supplemental coverage face tremendous financial challenges; they could accrue bills totaling 20% of the cost of treatment indefinitely based on therapies covered via Medicare Part B. According to Medicare Payment Advisory Commission (MedPAC), approximately 9% of Medicare beneficiaries have no source of supplemental coverage to alleviate this financial burden. Some physicians have continued to treat patients in their offices, despite the patients' inability to meet the cost-sharing requirements. The result has been a financial liability for the practice. Costs associated with newer, innovative therapies will likely impact choices regarding therapy for cancer. Although newer therapies may have fewer side effects and improved remission and survival rates, the cost of care is considerably higher. Patients and the oncologists who treat them are left with very difficult decisions, including uncertainty about response to treatment that will mimic the efficacy rates in clinical trials and the high cost of the newer drug therapy options. Many practices, having incurred a liability by continuing to treat beneficiaries who cannot meet the cost-share, are beginning to counsel patients before treatment about the real or potential financial burden.[12]

But increasingly, the concern is not only the uninsured but also the underinsured: patients who have coverage, but cannot afford their out-of-pocket responsibilities. Manufacturer-sponsored patient assistance programs have traditionally offered coverage to uninsured patients. More recently, copayment assistance foundations—bona fide, independent charities, often called "cost-sharing assistance models" or "copay assistance foundations"—have entered the health care milieu to provide assistance. CMS and the Office of the Inspector General have reviewed and endorsed this new model and developed a set of rules and guidelines by which these foundations must be developed and administered. These foundations do not provide drug-specific assistance but, rather, assistance across disease states without regard to specific products or manufacturers. Monetary donations from pharmaceutical manufacturers and other interested groups are pooled and designated for specific disease categories; patients with high-burden diseases then seek funding from this pool. Many foundations are focusing on CRC (Table 2) and finding ways to assist CRC patients with out-of-pocket requirements.

Summary

CMS, vis-à-vis the Medicare coverage process, is examining and implementing ways to continue providing access to therapies as the evidence about safety, efficacy, and effectiveness

TABLE 2 Copayment Assistance Foundations

Program	Disease Areas *	Telephone Number
HealthWell Foundation (www.healthwellfoundation.org)	• Chemotherapy-induced neutropenia • Myelodysplastic syndromes (MDS) • Non-Hodgkin's lymphoma • Non-small cell lung cancer • Chemotherapy-induced anemia • Colorectal carcinoma • Multiple myeloma	(800) 675-8416
NORD National Organization for Rare Disorders (www.rarediseases.org)	• Intrathecal therapy for pain management	(888) 744-2581
PANF Patient Access Network Foundation (www.patientaccessnetwork.org)	• Breast cancer • Colorectal cancer •Cutaneous T-cell lymphoma • Non-Hodgkin's lymphoma • Non-small cell lung cancer • Pancreatic cancer • Anemia • Chemo-induced nausea and vomiting • Oncology cytoprotection • Myelodysplastic syndrome • Multiple myeloma	(866) 316-PANF (7263)
PAF Patient Advocate Foundation (www.copays.org)	• Anemia/neutropenia secondary cancer treatment • Breast cancer chemotherapy • Kidney cancer • Colorectal cancer • Lung cancer • Lymphoma • Prostate cancer • Sarcoma	(866) 512-3861
PSI Patient Services Incorporated (www.uneedpsi.org)	• Chronic myelocytic leukemia	(800) 355-7741

** Not exhaustive list (see foundation Web sites or call toll-free number for complete details).*

accumulates. Over time, public policy makers and Medicare will have to make decisions about the sustainability of the path they have chosen from financial, policy development, and overall burden standpoints. The private industry's involvement in these processes will need to be assertive and forward-thinking, especially as expensive oral products become a more routine treatment choice. Patients' out-of-pocket expenses will force our health care systems to look for ways to ensure continuing access to therapies and reduce financial burdens as a cause for nonadherence, therapy cessation, and changing treatment decisions by providers and patients.

Update

The following is information regarding developments since the October symposium relevant to the previous discussion.

Medicare Physician Fee Schedule

The Medicare Physician Fee Schedule (MPFS) final rule was released November 1, 2006. According to the final ruling, which became effective January 1, 2007, the Medicare program substantially increased work values for Evaluation and Management (E&M) Services—effectively reimbursing physicians more for the time they spend talking with Medicare beneficiaries about their health care. The ruling also mandated reimbursement for and measures to eliminate barriers for a broader range of preventive services, including exempting the cost of the colorectal screening from Part B deductible.

Although the December ruling was to implement a 5% cut in physician payments and reduce the conversion factor, Congress's December 9, 2006, passage of the Tax Relief and Health Care Act overrode these directives, placing a moratorium on the cuts until the end of 2007.

The ruling maintained the current reimbursement rate of ASP+6% for Part B drugs administered in outpatient facilities. It did, however, clarify or address some outstanding ASP technical issues.[13] New drugs are paid at 106% of the wholesale acquisition

cost (WAC) until price data is collected.[14] CMS clarifies it will use the Medicaid definition of nominal sales—a price that is less than 10% of the average manufacturer price (AMP) in the same quarter for which the AMP is computed.

The CMS ruling did not finalize definitions for "bundled-priced concessions." The December 2007 proposed rule regarding the calculation of AMP and best price reporting[15] proposes to define the term "bundled sale" broadly as "an arrangement regardless of physical packaging under which the rebate, discount or other price concession is conditioned upon the purchase of the same drug or drugs of different types . . . or some other performance requirement . . . or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement."

Additionally, CMS proposes to require that discounts on bundled sales be allocated "proportionally to the dollar value of the units of each drug sold under the bundled arrangement . . . across all the drugs in the bundle." CMS was accepting comments on the proposed rule through February 20, 2007.[16]

Inconsistent Use of Administrative Codes

Recognizing a need to facilitate efforts toward consistent use of administrative codes, in November 2006, CMS and the National Center for Health Statistics released guidelines for coding and reporting using the *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM). The 102-page guideline document, developed in cooperation with the American Hospital Association (AHA) and the American Health Information Management Association (AHIMA), is intended to be used as a companion document to the official version of the ICD-9-CM as published on CD-ROM by the U.S. Government Printing Office. The guideline document is available online at http://www.cdc.gov/nchs/datawh/ftpserv/ftpicd9/icdguide06.pdf.[17] The CMS Web site maintains a listing of new, deleted, and revised codes available at http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/07_summarytables.asp#TopOfPage.

Additionally, an official process for requesting new/revised ICD-9-CM procedure codes has been implemented and is available at http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/08_ICD10.asp#TopOfPage.[18]

Donut Hole

Beginning January 1, 2007, beneficiaries reaching the donut hole became responsible for $3,850 in out-of-pocket total drug spending until the Medicare drug benefit begins covering 95% of costs. This represents a slight increase over the 2006 required total $3,600 drug spending.[19]

A study by the Kaiser Family Foundation investigating the impact of the donut hole on Medicare beneficiaries during 2006 found that nearly half of all Medicare beneficiaries, or 10.9 million people, were enrolled in plans that made them responsible for 100% of their drug spending when reaching the donut hole, and approximately 4 million beneficiaries had drug spending in 2006 inside the coverage gap.[20] Only about 12% of those beneficiaries had drug plans that helped with costs inside the donut hole, and about 60% of these beneficiaries had plans that covered only generic drugs. Of 266 companies offering donut hole Medicare drug plans in 2006, 10 accounted for 72% of the market.

In 2007, 85% of plans are offering comprehensive coverage, which includes the so-called donut hole coverage gap. Still, most (about 85%) of these plans providing gap coverage only cover generic drugs. And the average generic-only gap coverage monthly premium is $51.11 compared with the no-gap policy premium of $30.17. Brand/generic gap coverage premiums soar more than 3-fold higher than the no-gap coverage at $93.46.

More recent attention has been on the societal implications of the generic-only provisions of private insurance "gap" coverage.[21] Some beneficiaries, such as those with multiple sclerosis or rheumatoid arthritis, must take brand-name drugs because there are no generic alternatives. Las Vegas-based Sierra Health Services, the only major plan to cover brand-name drugs in the "gap" this year, reportedly lost $3 million in the first month of operation and was forced to cease its brand-name coverage option for 2008. Humana had a similar experience in 2006 when it tried to cover brand-name drugs in its gap policy. These experiences are only likely to reinforce plan decisions to circumvent the societal need for expanded gap coverage formularies in certain patient populations.[22]

Oncology Demonstration Project, Pay-for-Performance-Based Fee Bonuses

CMS's oncology demonstration project was not extended for 2007. At the time the project's discontinuation was announced, chief among the concerns was the loss of millions of dollars in compensation it has provided to physicians over its 2-year tenure. In this regard, CMS is counting on bonus payments to physicians who meet and report certain quality measures from July 1, 2007, to December 31, 2007, provided for in the Tax Relief and Health Care Act of 2006 (HR 6111) through the 2007 Physician Quality Reporting Initiative (PQRI).[23]

Those physicians who satisfactorily submit data will receive a payment equal to 1.5% of all allowed charges for the period between July 1, 2007, and December 31, 2007, subject to a cap. An aggregate dollar amount of $1.35 billion is the limit for 2008. The payment for 2007 will be a 1-time, lump-sum, after-the-fact payment. Claims may be submitted through the end of February 2008 for services rendered during the reporting period and the payment will not be forthcoming until after that time.

On April 3, 2007, CMS released detailed specifications for the 74 measures included in the 2007 PQRI. For a complete listing of specifications visit http://www.cms.hhs.gov/PQRI/Downloads/Specifications_2007-02-04.pdf

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