Proposed 2008 HOPPS Rule Released; ACCC Comments

On July 16, 2007, the Centers for Medicare & Medicaid Services (CMS) released the proposed 2008 Hospital Outpatient Prospective Payment System (HOPPS) Rule.

On the decidedly ugly side is CMS' proposal to reduce payment for many separately paid drugs to average sales price (ASP) + 5 percent in 2008. ACCC strongly disagrees with CMS' conclusion that these rates will be adequate to reimburse hospitals for the costs of both acquiring and preparing drugs for administration, and is urging the agency to address serious flaws in its calculations. Note that this proposal was in place in last year's HOPPS proposed rule, only to be criticized by a majority of stakeholders and the Ambulatory Payment Classification (APC) Advisory Panel, all of which recommended the level to remain at least ASP+6 percent. For CMS to once again make this proposal seems to discount all of the advice and recommendations CMS received last year from these esteemed stakeholders.

CMS claims that the proposed ASP+5 percent will be sufficient to cover hospitals' acquisition costs as well as pharmacy handling costs. A survey of ACCC members conducted last year indicates that this may not be true. Over half of the survey respondents said that the proposed rates would *not* be adequate reimbursement for the costs of providing five commonly used oncology and supportive care drugs. ACCC believes survey findings would be the same, if not worse, this year.

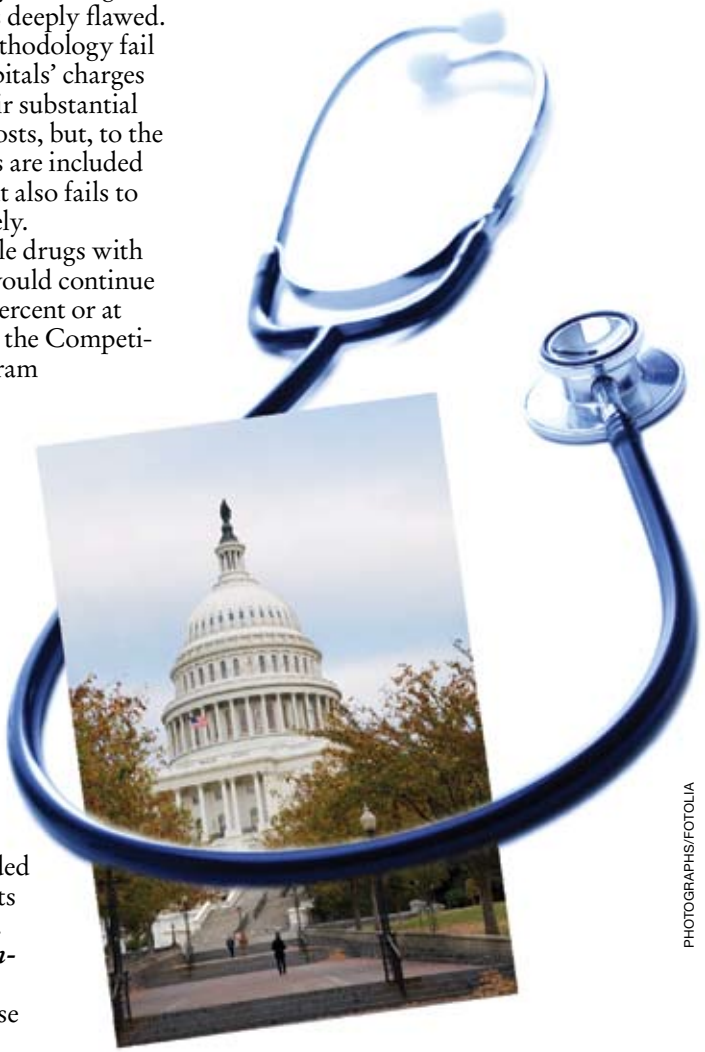
CMS rejected the proposal put forward by ACCC and other stakeholders and endorsed by the APC Advisory Panel to devise a three-phase plan for creating separate payment for pharmacy handling costs. CMS found this proposal inconsistent with its goal of increasing packaging. Further, the agency said its claims data accurately reflected both acquisition and overhead costs. For 2008 CMS proposes to require hospitals to remove pharmacy overhead charges from the charge for the drug, and to report those charges on an uncoded revenue code line. Hospitals would have the choice to report a charge per drug or per episode of drug administration services. In the future, CMS would package those charges into associated procedures, such as drug administration services.

ACCC believes that CMS' methodology for determining payment rates for separately payable drugs and their handling costs is deeply flawed. Not only does the methodology fail to recognize that hospitals' charges might not include their substantial pharmacy handling costs, but, to the extent that those costs are included in hospitals' charges, it also fails to capture them accurately.

In the proposed rule drugs with pass-through status would continue to be paid at ASP+6 percent or at rates applicable under the Competitive Acquisition Program (CAP), the same rates as apply in physician offices. In 2008, 13 drugs are proposed to have pass-through status, while the pass-through status of 7 drugs will expire.

ACCC is urging CMS to recalculate payment rates and set payment in 2008 at no less than ASP+6 percent, the rate applicable in physicians' offices, as recommended by the APC Panel at its August 2006 meeting.

Packaging and bundling. For 2008, CMS is proposing to increase its packaging and bundling policies because they provide "greater incentives for efficiency," while allowing hospitals maximum flexibility in using resources and not creating "beneficiary access issues." The agency defines packaging as including payment for one item or service in payment for another, such as including payment for a drug in the payment for the administration service. CMS defines bundling as making a single payment for a group of items and services furnished during an encounter. The packaging threshold for drugs would be increased to $60



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per day—compared to $55 in 2007 and $50 in 2006. In other words, any drug whose average cost per day is less than $60 will be packaged into the payment for the drug administration service. Anti-emetics continue to be exempt from packaging; CMS proposes to continue to pay separately for 5HT3 anti-emetics—regardless of their cost per day.

While ACCC commends CMS' proposal to pay separately for anti-emetics, the Association is concerned that increasing the packaging threshold could reduce the number of drugs that are separately paid and could harm beneficiary access to appropriate care. Additionally, unpackaging these drugs would help to improve the overall accuracy of the HOPPS. An analysis of the claims data found that only 4 percent of claims for packaged drugs are submitted with a drug administration claim and are used to set rates for these services. Over 40 percent of the claims for packaged drugs were submitted with claims for other services, and more than half of the claims for packaged drugs are not used in CMS' analysis. This indicates that the costs of packaged drugs are not actually included in payment for drug administration services, although they are included in the HOPPS. Paying separately for these drugs would help CMS to calculate more accurate payments for all of the services in which drugs are used.

Paying separately for all drugs with HCPCS codes also would eliminate disparities between the hospital outpatient and physician office settings and would not provide financial incentives to use more costly separately paid drugs even when a bundled drug may be more clinically appropriate. Most hospitals currently code for bundled drugs, so billing for them separately would not create a substantial additional administrative burden.

Drug administration services. CMS proposes to keep the current APC structure for drug administration services. The proposed payments for drug administration services are 1.6 percent to 26 percent more than the 2007 rates, with most chemotherapy codes increasing by 1.6 percent to 12.2 percent. The agency chose not implement the APC Panel's recommendation to make separate payment for concurrent infusions (90768), and would continue to package payment for those services into payment for other infusions.

Radiopharmaceuticals and contrast agents. Therapeutic radiopharmaceuticals would be paid separately if average cost per day is greater than $60. CMS would establish rates based on the mean costs derived from 2006 claims data, using CMS' standard methodology. This method is a change from the current one of paying based on a hospital's charges reduced to cost.

CMS proposes to package payment for diagnostic radiopharmaceuticals and contrast agents—regardless of their cost per day. The agency views these products as supplies provided in support of an independent service, not an independent service in their own right. Payments for the diagnostic or imaging service increase, but the increase might not be sufficient to cover the costs of the radiopharmaceutical or contrast agent. ACCC is concerned that CMS' proposed payment rates for radiopharmaceuticals will be inadequate to protect beneficiary access to important cancer therapies. Radiopharmaceuticals are extremely complex therapies to prepare and administer and require a unique bundle of services. The costs of these services vary for each therapy, and many of these costs are not reimbursed under the HOPPS.

ACCC believes CMS' proposed methodology for setting payments for radiopharmaceuticals is flawed, because it fails to adjust for charge compression and relies on incomplete data. In its comments, ACCC expressed disappointment that CMS is not waiting for hospitals to adjust their charges so it will have more accurate data on which to base payments.

ACCC noted in its comments to CMS that if the HOPPS does not appropriately reimburse for all of the costs of providing radiopharmaceuticals, hospitals will not be able to continue to provide these advanced treatments. Of particular concern is ensuring access to therapeutic radiopharmaceuticals, such as Bexxar® and Zevalin®. The rates calculated through the proposed methodology will be substantially reduced from 2007 levels, possibly below hospitals' acquisition costs. Faced with reduced payment for the radiotherapies, many hospitals may not be able to offer these therapies in 2008.

ACCC is urging CMS to continue to use the 2006 payment methodology for radiopharmaceuticals for at least one more year and to evaluate the data at the end of that year to determine how to set rates in the future. According to CMS, this methodology protects against rapid reductions that could harm beneficiary access to these therapies.

Packaging of ancillary services. CMS proposes to package payment for the following seven categories of supportive ancillary services into payment for the primary diagnostic or therapeutic procedure:

1. Guidance services
2. Image processing services
3. Intraoperative services
4. Imaging supervision and interpretation services
5. Diagnostic radiopharmaceuticals
6. Contrast agents
7. Observation services.

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Generally payments for the primary procedure have been increased, but the increase might not equal the 2007 payment for the separate procedures. For example, payment for percutaneous breast biopsy (CPT 19102) would increase from $240 to $465, an increase of $225. However, in 2008, the payment for placement of a localization clip and imaging guidance would be packaged into payment for the biopsy. In 2007, payment for those ancillary procedures ranges from $104 to $279. The proposed payments for the combined procedures may be less than the current separate payments these procedures.

E&M coding and payment for visits. The proposed payment rates for visits are 4 to 5 percent more than the 2007 rates. CMS does not propose national guidelines for coding for outpatient visits, but instead will continue to permit hospitals to report visits

using their own internal guidelines. If the agency decides to implement national guidelines in the future, it will provide at least 6 to 12 months notice. CMS requests comments on whether there is a "pressing need for national guidelines" or if the current system of hospitals creating their own internal guidelines is sufficient. The agency thinks it is unlikely that a single set of guidelines could apply to all hospitals and specialty clinics. CMS states that hospitals' internal guidance should comport with the following 11 principles. Specifically, the coding guidelines should:

- Be designed to reasonably relate the intensity of hospital resources to the different levels of effort represented by the code.
- Be based on hospital facility resources—not physician resources.
- Facilitate accurate payments and be usable for compliance purposes and audits.
- Meet HIPAA requirements.
- Require documentation that patient care is clinically necessary.
- Not facilitate upcoding or gaming.
- Be written or recorded, well-documented, and provide the basis for selection of a specific code.
- Be applied consistently across patients in the clinic or emergency department to which they apply.
- Be readily available for fiscal intermediary or MAC review.
- Result in coding decisions that could be verified by other hospital staff, as well as outside sources.
- Not change with great frequency.

Quality measures. CMS requests comments on several quality measures that could be implemented for 2010 and subsequent years. These measures include several oncology-related standards, such as provision of radiation therapy within 1 year of diagnosis for women under age 70 receiving breast conserving therapy; adjuvant chemotherapy administered within 4 months of surgery for patients with AJCC colon cancer; and adjuvant hormonal therapy for treatment of breast cancer.

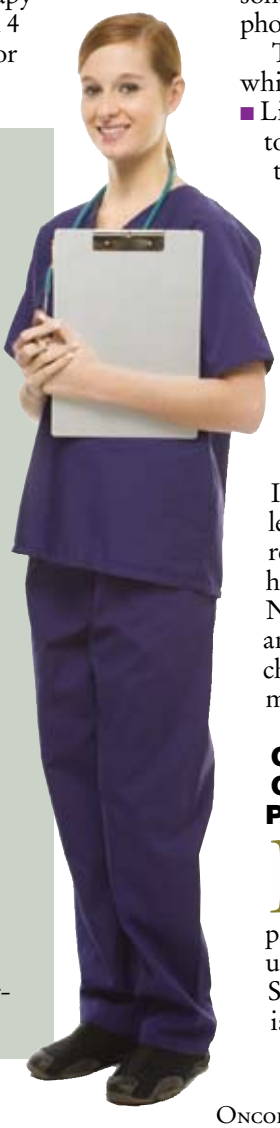
ACCC Survey Reveals Hospital Concerns over Potential Changes to ESA Policy

A recent survey of ACCC-member hospitals found that four out of five respondents are concerned about the potential impacts that a change in access to erythropoiesis stimulating agents (ESAs) may have on hospital resources and services.

"When CMS released the proposed coverage determination [NCD] on ESAs in May, we had numerous concerns," said Christian Downs, JD, MHA, ACCC executive director. "One issue that we believed may not have been getting the attention it needed was the impact on hospitals, which are going to bear the brunt of increased blood transfusions."

ACCC's survey was designed to measure how much of an increase in the number of blood transfusions would strain hospital resources and services, such as blood supply, bed space, personnel, and equipment. Forty-one percent of survey respondents indicated that an increase in blood transfusions of 30 percent would cause a problem in carrying out normal operations. Another 16.5 percent responded that even a 10 percent or less increase would cause a problem, and about 22 percent of respondents indicated that any increase would result in a problem.

ACCC shared these survey results with CMS before the agency released its final NCD in August. For complete survey responses, go to *www.accc-cancer.org*.



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CMS Issues Final NCD for Use of ESAs in Cancer Care

On July 30 CMS released a final national coverage determination (NCD) for Erythropoiesis Stimulating Agents (ESAs). The agency no longer distinguishes between those cancers that have erythropoietin receptors and cancers without such receptors. In addition, CMS has made no determination regarding ESA use for myelodysplastic syndrome (MDS). In cases where no determination is made, Medicare local contractors have the discretion to make reasonable and necessary determinations regarding ESA use.

The final NCD provides coverage with restrictions for the treatment of anemia secondary to myelosuppressive anticancer chemotherapy in certain cancer conditions, such as solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia.

The NCD details restrictions, which include:

- Limiting initiation of ESA therapy to when the hemoglobin level is less than 10g/dL
- Limiting ESA treatment duration to a maximum of 8 weeks after a chemotherapy session ends
- Limiting the starting dose to the FDA-recommended starting dose
- Limiting dose escalation levels.

In August, ACCC submitted a letter to CMS asking the agency to reopen the NCD on ESAs. ACCC has major concerns with the final NCD and believes more study and analysis are needed before major changes are made to reimbursement of ESAs.

CMS Releases Proposed Changes to Medicare Physician Fee Schedule

Released July 2, the 2008 proposed rule would make a number of changes to payments for specific services paid under the Medicare Physician Fee Schedule. For example, the agency is proposing to revise the meth-

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odology for determining the average sales price (ASP) for Part B drugs by "defining bundled arrangements and requiring that drug manufacturers allocate bundled price concessions proportionately to the dollar value of units of each drug sold under the bundled arrangement when reporting ASPs."

CMS is also proposing to continue to pay for preadmission-related services for intravenous infusion of immunoglobulin (IVIG) under a temporary HCPCS code, G0332. This payment is for the extra resources expended in locating and obtaining IVIG products that are appropriate for the patient's treatment, and for scheduling the patient's infusions. This service may be billed for each visit to the physician's office at which IVIG is administered.

The rule proposes adopting the recommendations of the American Medical Association's Relative Value Update Committee (RUC) with regard to more than 50 procedures that were included in the 2007 five-year review of work, but for which a decision was deferred until the 2008 proposed rule.

CMS proposes to maintain budget neutrality associated with the work RVU changes in the proposed rule by adjusting the work RVUs of all services, rather than by adjusting the conversion factor. This method allowed the agency to maintain budget neutrality for the 2007 fee schedule.

In its proposed rule, CMS outlined measures from seven categories for inclusion in the 2008 Physician Quality Reporting Initiative (PQRI)—provided that the measures are either endorsed by the National Quality Forum (NQF) or adopted by the AQA Alliance. The proposed rule would also retain the 2007 PQRI measures endorsed by NQF.

Other provisions in the proposed rule include:

- Requiring the reporting of hemoglobin or hematocrit data on claims for drugs used to treat anemia secondary to anticancer treatment.
- Modifying a number of physician self-referral provisions to close loopholes that have made the Medicare program vulnerable to abuse.

As required by the sustainable growth rate (SGR) formula, Medicare physician payments will decline by 9.9 percent in 2008. However, Congress is expected to intervene—as it has in the last five years—to prevent the implementation of the negative updates.

CMS Releases New Proposed Clinical Trial Policy

On July 19 CMS released a new proposed clinical trial policy. The new tracking sheet and the proposed policy are available on the CMS website at *www.cms.hhs.gov/*. ACCC reviewed the proposal and submitted comments to CMS relaying the Association's concerns regarding the potential impact of the new proposed policy on Medicare patients enrolled in clinical trials.

The new action follows a July 9 CMS final Clinical Trial Policy Decision Memorandum on coverage of items and services used by beneficiaries in clinical trials, which made few changes to the existing policy. CMS said that this new proposed policy builds upon the input received while the agency was developing the July 9 final policy.

The agency said its new proposal clarifies the standards that CMS believes are important to patient safety and good outcomes. "It also allows study sponsors or principal investigators to certify that their study has met these standards," the agency said.

CMS scheduled an Open Door Forum on Aug. 7 on this action. CMS plans to issue a final decision memorandum by Oct. 19.

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NCI Launches Pilot Program

The National Cancer Institute (NCI) has launched the pilot phase of its Community Cancer Centers Program, an initiative that aims to bring the latest advances in cancer care to patients where they live. The project will focus on underserved communities and groups that are disproportionately affected by the disease. Over the next three years, 16 community hospitals will work together and with NCI to identify the best strategies for delivering state-of-the-art cancer care in community hospitals. A successful pilot could lead to a national network of community cancer centers that would benefit patients and researchers alike.

The pilot study is intended to define the critical factors that will allow community cancer centers to provide patients with advanced care. "In the next few years, we hopefully will learn what we can accomplish and what is realistic," said NCI Director, John E. Niederhuber, MD.

Most of the institutions that are participating in the project are ACCC-member institutions, including the Gibbs Cancer Center located at the Spartanburg Regional Medical Center in Spartanburg, S.C. (below). For a full listing of these participating institutions or to learn more about this initiative, go to *http://ncccp.cancer.gov*.

Are Medicaid Crossover Payment Policies Affecting Patient Care?

by Amy J. Demske

Over the years, state Medicaid programs have been responsible for picking up co-insurance and covered services not covered by Medicare for those patients eligible for both programs. The extent of a state's liability for dual eligibles has evolved since the passage of the Balanced Budget Act of 1997, which allows state Medicaid programs to cap their payments for dual eligibles at the "Medicare allowable" amount for services as long as their payment policies are written in their state plan. As a result, some states have capped their liability so that providers receive no more than the state would have paid if the beneficiary had only Medicaid coverage. The problem with this practice: state payment levels are often too low to adequately compensate physicians for the services they provide to the poorest Medicare patients.

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The 2003 Medicare Modernization Act (MMA), with its resultant prescription drug benefit and Medicare Part B drug payment reform, has significantly compounded this issue. It is unclear whether drafters of the MMA fully considered the financial burden that the Medicare drug benefit would place on state Medicaid programs, which are required to pay the federal government most of the savings realized from no longer having to provide prescription drugs to dual eligibles. Changes in Medicaid payment responsibility for dual eligibles coupled with budget shortfalls in state Medicaid programs over the past few years have only increased the pressure on states to significantly limit reimbursement for healthcare services.

Physicians in Tennessee, for example, have reported patient access issues resulting from TennCare's policies pertaining to the coordination of benefits for dual eligible patients, which reads as follows:

"If third party [Medicare] payment is less than the Medicaid allowable, Medicaid will pay the difference between the third party payment and the Medicaid allowable. No further claim shall be allowed…If third party payment is equal to or exceeds the Medicaid allowable, no further claim shall be allowed against Medicaid…"

The practical application of this policy is most detrimental to overall reimbursement for physician administered drugs. Using the TennCare example, if the current "Medicare allowable" is $1,000 for a particular drug therapy, but Medicare actually pays $800 (or 80 percent) of that amount, providers expect that the 20 percent balance would be paid by TennCare. Unfortunately, TennCare has lowered the "Medicaid allowable" amount for the drug to 80 percent of the "Medicare allowable" amount from levels that historically were equal to or greater than Medicare to encourage broad physician participation in Medicaid. Now, providers in Tennessee and other states that have adopted this tact must absorb the $200 balance for physician-administered drugs.

As a result of the MMA, the standard Medicare payment rate is based on average sales price (ASP) data—which is currently set at 106 percent of ASP—that manufacturers furnish to Medicare each quarter. Physician acquisition and handling costs for these drugs are typically at or above the ASP rate. Reimbursement limited to an 80 percent payment of the ASP-based allowable is clearly insufficient to cover a physician's acquisition cost for the product. Though state policies limiting Medicare and Medicaid crossover payments are not new, Medicare Part B drug payment reform has exacerbated the problem significantly. Physicians could more easily absorb the losses on drugs resulting from these Medicaid payment policies prior to the MMA; those losses are much harder to swallow now.

For people with cancer, this policy may affect their access to certain therapies. Oncologists who would like to administer a specific therapy to their lower-income Medicare patients often face difficult decisions with regard to the cost of that care. In many cases, these physicians must either accept losses for these drugs, prescribe alternative (and sometimes less efficacious) therapy options, or refer long-time patients to the hospital setting to receive and/or continue their care.

Medicaid policies affect the decisions that healthcare providers are forced to make about the delivery of life-sustaining medical care. Unfortunately, the state response to the federal mandates is adversely affecting those persons in the most need of services—the poor and the sick. If you would like to share stories of how "crossover" policies in your state are affecting your practice, please contact: *demske.amy@arentfox.com*

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