THE ISSUES

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18-Month SGR Fix in the Works

In April the Senate Finance Committee and representatives from various physician specialty groups met to discuss the upcoming 10.6 percent cut to the SGR formula due to take effect July 1, 2008, if Congress does not act. Based on information presented at this meeting, it appears that Senator Baucus (D-MT), Chairman of the Finance Committee, is in favor of an 18-month fix, and hopes to have a bill in place by mid-May. It is possible that provisions for mandatory e-prescribing and additional funding for the Physician Quality Report Initiative (PQRI) may be included in the 18-month physician payment fix. Any temporary fix will be expensive and offsets were not discussed at the meeting. According to a Finance Committee memo released after the meeting, "Chairman Baucus intends to pursue an 18-month fix this spring, which will be longer than the previous three fixes" (dating back to the Deficit Reduction Act). Getting an 18-month fix will be very difficult, however, because all potential offsets are controversial.

ACCC is continuing to meet with members of the Finance Committee in hopes of adding a provision to this Medicare fix that would address the declining drug reimbursement in the hospital outpatient setting.

ACCC Continues to Work on ASP Fix for Hospitals

This year drug reimbursement in the hospital outpatient department has been reduced to average sales price (ASP) +5 percent, and the Centers for Medicare & Medicaid Services (CMS) plans to lower it to ASP +3 percent in 2009. ACCC continues to garner support for its drug reimbursement legislative fix by visiting members of the U.S. Senate. In addition, ACCC and a coalition of other organizations have sent a letter to Congress urging a return to ASP+6 percent in the hospital outpatient setting.

In April ACCC visited with members of the Senate Finance Committee, including the offices of Senator Sununu (R-NH), Senator Bunning (R-KY), Senator Crapo (R-ID), Senator Hatch (R-UT), and Senator Roberts (R-KS). We are nearly finished meeting with the committee members, and we still need your help.

We ask for the support of ACCC membership by signing on to our coalition letter. To read the letter go to: *http://www.accc-cancer.org/publicpolicy/pdf/ASPlettermarch2008.pdf*. If you would like to add your name to this effort, please email Matt Farber at *mfarber@accc-cancer.org*.

Update on Drug Compendia

As reported in the March/April 2008 *Oncology Issues*, CMS received four requests to add additional compendium to the list of approved references for coverage of off-label drugs. The agency is expected to make its decision no later than early July. Each application has been assigned a different decision deadline:

1. The National Comprehensive Cancer Network (NCCN) *Drugs & Biologics Compendium*: June 6.
2. Thomson Micromedex's *DrugPoints*®: June 10
3. Thomson Micromedex's *DrugDex*®: June 17
4. The *Clinical Pharmacology Compendium*: July 2.

During an April 10 audio conference sponsored by Avalere Health, Louis Jacques, director of the Division of Items and Devices in Coverage and Analysis at CMS, said the agency does not plan to consider appeals of its decisions.

Proposed—A $4 Billion Payment Increase for Inpatient Hospital Care

Medicare payments to hospitals participating in the program's inpatient prospective payment system would increase by about $4 billion in fiscal 2009, under a proposed rule issued April 14 by CMS that also takes steps to improve the quality of care offered by hospitals. In addition to increasing hospitals' Medicare reimbursement, the proposed rule would raise from 8 to 17 the number of hospital-acquired conditions Medicare will no longer pay additional money for, and would add 43 quality measures to the 30 already required for hospitals to report to CMS to receive a full payment update.

Comments on the 1,200-page proposed rule, scheduled to be published in the *Federal Register* April 30, are due by June 13. The rule

continued on page 8

would affect 3,528 hospitals. The average payment per case would rise from $9,144 in fiscal 2008 to $9,519 for fiscal 2009, or a 4.1 percent increase, according to the agency. The changes would apply to services provided to beneficiaries beginning Oct. 1. CMS said it expects to issue a final rule by Aug. 1.

CMS is also proposing to refine its hospital transfer policy. Currently, if a patient is transferred from an inpatient hospital prior to the geometric mean length-of-stay for certain diagnosis-related groups and receives services from a home health agency within three days, the hospital is paid on a per diem rate rather than the full diagnosis-related group payment under the inpatient PPS. CMS in the proposed rule wants to extend the timeframe from three days to seven days, effective Oct. 1.

The proposed rule is available online at: *www.cms.hhs.gov/AcuteInpatientPPS/downloads/CMS-1390-P.pdf.*

New! e-Prescribing Standards for Drug Benefit Program

CMS has finalized four new standards for e-prescribing in the Medicare Part D drug benefit. Although e-prescribing will be optional for physicians and pharmacies, Medicare will require drug plans participating in the new prescription benefit to support electronic prescribing. The final e-prescribing rule was published in the *Federal Register* on April 2, 2008. The four standards include:

1. ***Formulary and benefit transactions*** give prescribers information about which drugs are covered by a Medicare beneficiary's prescription drug benefit plan.
2. ***Medication history transactions*** provide prescribers with information about medications a beneficiary is already taking, including those prescribed by other providers, to help reduce the number of adverse drug events.
3. ***Fill status notifications*** allow prescribers to receive an electronic notice from the pharmacy telling them that a patient's prescription has been picked up, not picked up, or has been partially filled, to help monitor medication adherence in patients with chronic conditions.
4. Adoption of the ***national provider identifier (NPI)*** for e-prescribing under Medicare Part D. In addition, NCPDP SCRIPT 5.0 was retired in favor of the upgraded NCPDP SCRIPT 8.1

Oncology Pharmacist Takes Helm at ACCC

Ernest R. Anderson, Jr., MS, RPh, became President of the Association of Community Cancer Centers (ACCC) at its 34th Annual Meeting on April 4, 2008. He is director of pharmacy at the Lahey Clinic in Burlington, Mass., as well as the Lahey Clinic North in Peabody. Mr. Anderson is also associate clinical professor of pharmacy at Northeastern University College of Pharmacy and Allied Health Professions and adjunct associate professor of pharmacy at Massachusetts College of Pharmacy and Health Sciences in Boston.

Ernest R. Anderson, Jr.

"I am honored to serve as President of the Association of Community Cancer Centers," said Mr. Anderson. "Our common goal and calling is to provide excellent and effective care to our patients. To that end, we must help ensure that all patients with cancer can access breakthrough treatments if we are to truly increase cure rates, improve quality of life, and assure happiness and satisfaction of patients."

Mr. Anderson is the first pharmacist to serve as ACCC President and was the first pharmacist on ACCC's Board of Directors. Working with the Association's Executive Director, he helped create the Oncology Pharmacy Education Network (OPEN)—a network for oncology pharmacists to share experiences, business models, and successes. An advisory committee was created within OPEN, with Mr. Anderson as its chair.

During his term as President, Mr. Anderson will continue to encourage greater involvement in the Association by oncology pharmacists. In addition, he will promote the value of leadership skills among all ACCC members. "Leadership starts with valuing the people you work with every day—believing in their potential until they see it themselves. We need to ignite the fire of worth and potential in others. This will encourage all caregivers to provide the best for their patients."

Stark Update: CMS May Issue New Guidance

CMS may issue more interpretive and subregulatory guidance to hospitals and doctors on the physician self-referral rule, according to CMS Technical Payment Division Director Donald H. Romano. At the American Conference Institute's Symposium on Healthcare Fraud Investigations in April, Romano also said he would like to see the agency communicate to healthcare providers. One idea under consideration: special Stark alerts that would address specific self-referral issues as they arise, such as common questions from providers or questionable arrangements in place at multiple facilities. On the issue of CMS advisory opinions, Romano said that the agency hopes to shorten the time it takes to return opinions—a move which CMS hopes will encourage more providers to seek Stark advisory opinions.

Clinical Trials Coding Update

by Cindy C. Parman, CPC, CPC-H, RCC

The Centers for Medicare & Medicaid Services (CMS) began reimbursing for routine services performed in connection with clinical trials in calendar year (CY) 2000, but recently the agency has suspected that it has been reimbursing for services that are not "routine" care. As a result, CMS has implemented changes to the reporting of services performed in connection with approved clinical research studies. These changes are effective for CY 2008.

Modifier Changes—Effective January 1, 2008

CMS issued MLN Matters #MM5805 on January 18, 2008, updating the HCPCS Level II modifiers required on claims for patient care performed in clinical research studies.[1,2] In conjunction, Transmittal 74 was issued to Medicare contractors with instructions for claim processing updates. According to these documents, the agency has deleted modifiers –QA, –QR and –QV, and created two new modifiers for clinical trial claim submissions: Q0 and Q1.

Q0: *Investigational clinical service provided in an approved clinical research study*. This modifier replaces modifiers –QA and –QR.

Investigational clinical services are further defined as those items and services that are being investigated as an objective within the study. In addition, any services performed solely to satisfy data collection and analysis needs are to be reported with this modifier. For example, if a patient would normally receive a CT scan prior to treatment and another scan subsequent to treatment, but the trial sponsor indicates that monthly CT scans should be performed to track the progress of the treatment, these monthly scans will be reported with the –Q0 modifier.

Although Medicare expects that *all* services provided to the patient—both routine and investigational—will be submitted on the claim form, CMS will *not* reimburse for services reported with modifier –Q0.

Q1: *Routine clinical service provided in an approved clinical research study*. This modifier replaces modifier –QV. CMS defines routine clinical services as those items or services that are:

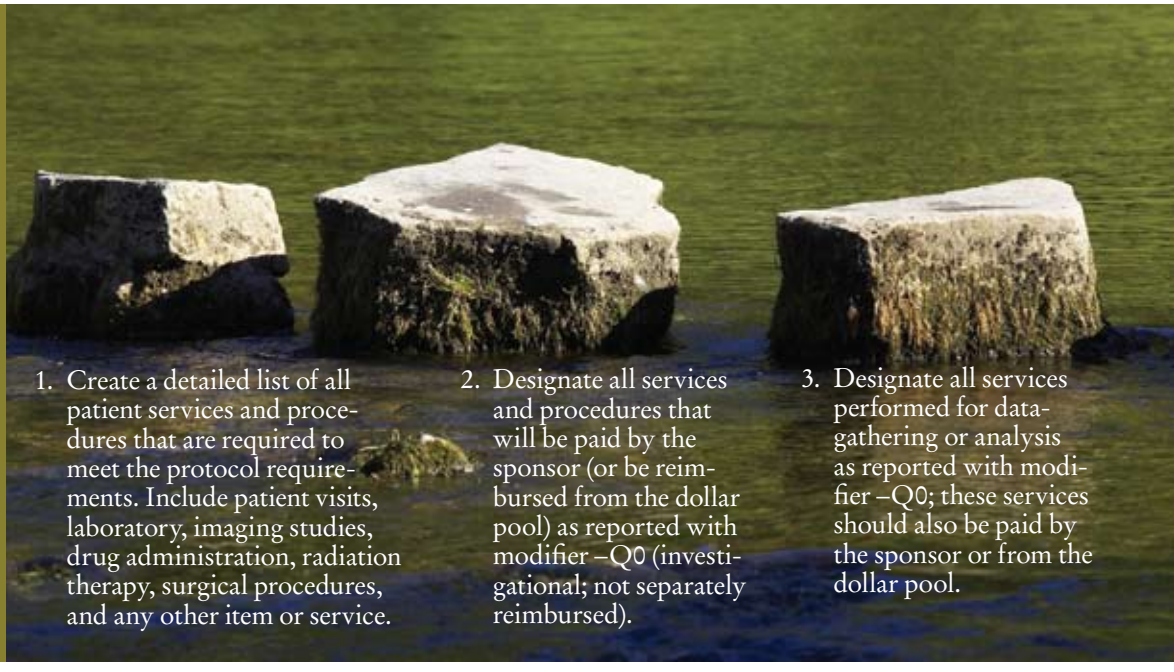
- Covered outside of the clinical research study;
- Used for the direct patient management within the study; and,
- Do not meet the definition of investigational clinical services.

Routine services include the clinically appropriate monitoring of the investigational item or procedure, the prevention of complications, and the treatment of any complications that arise from the investigational treatment.

Take note: if a cancer center or cancer program is managing a clinical trial patient, it falls to the staff in this department to notify the laboratory, imaging center, and any other medical entity that interacts with the

Billing Research Services

To determine which clinical research services will be reimbursed by insurance, follow these steps:



1. Create a detailed list of all patient services and procedures that are required to meet the protocol requirements. Include patient visits, laboratory, imaging studies, drug administration, radiation therapy, surgical procedures, and any other item or service.
2. Designate all services and procedures that will be paid by the sponsor (or be reimbursed from the dollar pool) as reported with modifier –Q0 (investigational; not separately reimbursed).
3. Designate all services performed for data-gathering or analysis as reported with modifier –Q0; these services should also be paid by the sponsor or from the dollar pool.

patient of the clinical trial status. In addition, these ancillary providers must be alerted regarding correct modifier reporting (e.g., modifier –Q0 or modifier –Q1).

CMS has also updated criteria for clinical trial coverage, and Medicare will reimburse for routine services only after the trial's lead principal investigator certifies that the trial meets all criteria. Last, although these modifier changes were effective January 1, 2008, Medicare contractors must implement the change no later than April 7, 2008.

Clinical Trial Registry Number

These modifier changes are not the only update to clinical trial claim submissions. CMS also issued MLN Matters #MM5790 on January 18, 2008 addressing the use of the 8-digit clinical trial registry number on claims.[3,4] This number can be voluntarily reported beginning April 7, 2008. The agency indicates that this information will help CMS inform beneficiaries about trial availability and allow it to use claims information to update coverage decisions.

The clinical trial number that CMS is requesting to be voluntarily reported is the number assigned by the National Library of Medicine (NLM) Clinical Trials Data Bank when a new study is registered by a sponsor or investigator. CMS will then use this number to identify all items and services provided to patients during their participation in a clinical trial.

Claim Form Submission

Institutional clinical trial claims submitted on the UB04 claim form are identified through the presence of *all* four of the following elements:

1. Value Code D4 (on the paper claim UB04, Form Locators 39-41) or for the electronic claim in Loop 2300, HI – VALUE INFORMATION segment, qualifier BE, and corresponding 8-digit clinical trial number (voluntary)
2. ICD-9-CM diagnosis code V70.7 (examination of participant in clinical trial)
3. Condition code 30
4. HCPCS Modifiers –Q0 or –Q1 for outpatient claims.

For freestanding cancer centers and professional claims submitted on the CMS 1500 claim form, the following three elements are mandated:

1. The clinical trial registry number should be preceded by the two alpha characters of "CT" and placed in field 19 of the paper Form CMS-1500. Or, the clinical trial registry number should be entered without the "CT" prefix in the electronic 837P in Loop 2300 REF02 (REF01=P4). (voluntary)
2. ICD-9-CM diagnosis code V70.7
3. HCPCS Modifiers –Q0 or –Q1.

The use of the new clinical trial modifiers (–Q0 and –Q1) are required for all clinical trial services billed beginning January 1, 2008. Local Medicare contractors have been encouraged to provide this updated clinical trial information to all providers and may include more detailed claims submission guidelines. Remember that while Medicare reimburses for routine clinical trial services, not all insurance payers will provide reimbursement for procedures performed as part of a clinical trial; individual payer policies should be obtained and followed for these services.

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References

[1]Centers for Medicare & Medicaid Services. New healthcare common procedure coding System (HCPCS) modifiers when billing for patient care in clinical research studies. *MLN Matters.* MM5805. Released Jan. 18, 2008. Available online at: *http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5805.pdf.* Last accessed April 10, 2008.

[2]Centers for Medicare & Medicaid Services. *New HCPCS Modifiers when Billing for Patient Care in Clinical Research Studies.* Transmittal 1418. Available online at: *http://www.cms.hhs.gov/Transmittals/downloads/R1418CP.pdf.* Last accessed April 10, 2008.

[3]Centers for Medicare & Medicaid Services. Use of an 8-digit registry number on clinical trial claims. *MLN Matters.* MM5790. Released Jan. 18, 2008. Available online at: *http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5790.pdf.* Last accessed April 10, 2008.

[4]Centers for Medicare & Medicaid Services. *Requirements for Including an 8-Digit Clinical Trial Number on Claims.* Transmittal 310. Available online at: *http://www.cms.hhs.gov/Transmittals/downloads/R310OTN.pdf.* Last accessed April 10, 2008.