The US Oncology Network Submits Comments to CMS Relative to the 2012 Medicare Physician Fee Schedule Proposed Rule

On August 30, Edward R. George, M.D., Chairman of National Policy Board of The US Oncology Network and practicing community oncologist with Virginia Oncology Associates, submitted comments to the Centers for Medicare and Medicaid Services (CMS) regarding the agency's proposed rule “Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2012” on behalf of the more than 1,000 oncologists of The US Oncology Network.

The comments address four key issues within the proposed rule: 1) Part B Drug Payments; 2) Average Sales Price (ASP) issues; 3) potentially misvalued services; and 3) transition to use of AMA Physician Practice Information Survey (PPIS) in determination of Resource-Based Practice Expense Relative Value Units (RBRVUs) and Quality Reporting Initiatives. These comments include the following recommendations:

- **Part B Drug Payments:** Urges CMS to defer its proposal to implement Average Manufacturer Price (AMP) substitution until it has published new AMP regulations, allowed manufacturers time to implement them, monitored the “new” AMP reports long enough to fine tune any safeguards to be built into the substitution process and ensured that AMP data is publicly available.

- **Potentially Misvalued Services:** Recommends creating an annual process through which stakeholders may nominate potentially misvalued codes for review and submit data to support those nominations regardless of whether the code at issue is presented as undervalued or overvalued.

- **Transition to Use of PPIS:** Encourages CMS to work with the AMA to conduct a new multispecialty survey that has increased statistical power, uses survey questions appropriately tailored to the specialty being surveyed, and is required to meet consistent precision standards for each specialty and use that data to refine the PPIS and the construction of the PFS for 2013.

- **Quality Reporting Initiatives:** Recommends that the Physician Quality Reporting System include an enhanced focus on high-quality, evidence-based cancer care by incorporating additional measures used as part of the American Society of Clinical Oncology (ASCO) Quality Oncology Practice Initiative® (QOPI®) into PQRS.

To view the comments of The US Oncology Network on the 2012 Medicare Physician Fee Schedule Proposed Rule, click here.

The US Oncology Network comments were submitted within a package of comments by McKesson Corporation. The US Oncology Network is supported by McKesson Specialty Care Solutions | US Oncology, a division of McKesson Corporation focused on empowering a vibrant and sustainable community patient care delivery system to advance the science, technology and quality of care.

To read the McKesson Corporation comments, click here.

Select Committee Selects Staff Director, Begins to Lay Groundwork for Task Ahead

On August 24, Sen. Patty Murray (D-WA) and Rep. Jeb Hensarling (R-TX), co-chairmen of the recently formed Joint Select Committee on Deficit Reduction (Select Committee), issued a statement announcing that the committee is now discussing its structure, organization and rules for operation as it will aim to cut $1.5 trillion from the federal deficit over 10 years.

Following this announcement, on August 30, the co-chairmen named Mark Prater, currently serving as deputy staff director and chief tax counsel on the minority staff of the Senate Finance Committee, as the Select Committee staff director.

In a statement released by Sen. Murray and Rep. Hensarling, the co-chairmen commended Prater’s work ethic and noted that in his more than 20 years serving on the Finance Committee, he has helped pass numerous pieces of bipartisan legislation impacting economic growth, tax, health care and employment.

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Select Committee Selects Staff Director, Begins to Lay Groundwork for Task Ahead (cont’d)

Created under the Budget Control Act of 2011 (BCA), the 12-member bipartisan committee will soon convene to consider budget cuts and revenue increases as it strives to develop its deficit-lowering plan by November 23 for passage in the House and Senate by December 23. In preparation for this plan, the panel members are reviewing previous deficit reduction efforts, which likely include components of President Obama’s discussions with House Speaker John Boehner (R-OH) as they attempted to achieve an earlier deal.

The Select Committee has not yet announced timing for its first meeting, which must be held no later than September 16 according to the BCA. The BCA also states that the committee’s first meeting must be open to the public. While several stakeholders have urged the committee to hold public meetings throughout the process, it is anticipated that the panel will hold both public hearings and closed-door meetings to accommodate private negotiations. The committee is also constructing a website that will provide the public with the opportunity to submit ideas and commentary.

The Select Committee is expected to hold its first official meeting in Washington upon Congress’ return to session after Labor Day.

REMINDER: Although the BCA does not specifically call for cuts to oncology reimbursement, a significant threat remains as the Select Committee develops its plan and as members develop the offsets needed to fund another fix to the nearly 30 percent Medicare physician reimbursement cuts scheduled for January 1, 2012.

Please continue to contact your Members of Congress and ask them to oppose Medicare cancer care cuts!

To contact your Members of Congress click here.

FDA Reports Increased Shortages of Life-Saving Cancer Drugs

The number of drugs with decreased or no availability has risen dramatically since 2010, according to the FDA, and 2010 had a large increase in such shortages from the year before.

Most of the drugs in short supply are generic injectables, used to treat life-threatening conditions such as breast, testicular and colon cancer. Among these are Doxil (doxorubicin), used off-label to treat breast cancer; cytarabine, used for leukemia treatment; and the chemotherapy drug cisplatin.

In some cases, prices for cancer drugs in limited quantity have increased by as much as twentyfold, and clinical trials for some new treatments have been delayed as the studies must also include some older medicines in short supply.

According to a June survey of 820 hospitals by the American Hospital Association (AHA), almost all of the surveyed hospitals had experienced at least one drug shortage within the previous six months, and almost half of the hospitals had experienced shortages of 21 or more drugs. Due to these shortages, more than 80 percent of the hospitals delayed needed treatments, almost 70 percent administered a less effective drug in substitution, and almost 80 percent restricted patient access to certain drugs.

In addition, a 2010 survey of 1,800 health care providers by the Institute for Safe Medication Practices determined that one-third of physicians and one-fifth of pharmacists surveyed knew of adverse patient outcomes due to drug shortages.

It is thought that a variety of factors are leading to these drug shortages – among them, contamination or capacity problems at some manufacturing plants, delays in receiving certain ingredients from suppliers and slowed investment in production of lower-profit generic drugs. Others have said the FDA is contributing to shortages by not inspecting plants quickly enough and not communicating adequately about shortages among its enforcement and shortages personnel.

As yet, Congress has not addressed this issue. However, bipartisan legislation proposed in the House and Senate would require that drug manufacturers provide the FDA with six months’ warning of problems that could disrupt access. (Continued on page 3.)

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FDA Reports Increased Shortages of Life-Saving Cancer Drugs (cont’d)

Accompanying this requirement would be strong penalties for noncompliance.

Other policy proposals include a national stockpile of medically important drugs, incentives for increased production of generics, and additional powers and resources for the FDA to address shortages – although such proposals to increase the FDA’s authority may be met with resistance by some lawmakers.

US Oncology has joined with other cancer care stakeholders in calling attention to the need for maintaining access to life-saving drugs in short supply, and held a Capitol Hill briefing with the Association of Community Cancer Centers (ACCC) and the Community Oncology Alliance (COA) on the need for reimbursement policies that facilitate patients’ access to effective anti-cancer treatments.

Policymakers have held a series of meetings addressing this issue in recent weeks, and more meetings are anticipated over the next month, including an FDA public advisory meeting and Congressional hearings.

CMS Announces Bundled Payments Initiative

On August 23, the Centers for Medicare and Medicaid Services (CMS) announced the Bundled Payments for Care Improvement initiative, a new bundled payment program for hospitals and physicians intended to better coordinate care, improve quality and lower costs.

The initiative, to be carried out by the agency’s new Center for Medicare and Medicaid Innovation (CMMI), will distribute payments for services provided throughout an episode of care rather than paying for separate services. It will allow providers to apply to help develop and test four different bundled payment models, and will give providers the flexibility to determine which episodes of care and which services will be grouped together.

The four payment models include:

- **Model 1: Acute care hospital stay only**
  - Hospitals to be paid a discounted amount based on the inpatient prospective payment system (IPPS) payment rates
  - Physicians to be paid separately for their services under the Medicare Physician Fee Schedule (PFS)
  - Hospitals and physicians allowed to share gains achieved from better care coordination

- **Model 2: Acute care hospital stay and post-acute care related to the stay**
  - Episode of care to end either a minimum of 30 or 90 days after discharge
  - To include physicians’ services, care by a post-acute care provider, related readmissions and other components of care such as clinical laboratory services, durable medical equipment and Part B drugs

- **Model 3: Post-acute care following discharge from an acute inpatient stay**
  - Episode of care to begin upon discharge and end no sooner than 30 days after discharge
  - To include physicians’ services, care by a post-acute care provider, related readmissions and other components of care such as clinical laboratory services, durable medical equipment and Part B drugs

- **Model 4: Single, prospective bundled payment for all services given during the inpatient stay by practitioners**
  - Bundled payment to the hospital to cover all services provided by the hospital, physicians and other providers
  - Physicians to submit “no-pay” claims to Medicare and be paid by the hospital out of the bundled payment

According to the *New England Journal of Medicine*, although the concept has substantial opportunity to align hospital and physician incentives and support quality care at lower costs, barriers to successful implementation of the bundled payment initiative lie within defining an episode of care (e.g., agreeing upon the number of days after discharge that it would end), persuading providers to accept the risk, and updating software and systems to automate the bundled payments. *(Continued on page 4.)*
CMS Announces Bundled Payments Initiative (cont’d)

The American Medical Association (AMA) has applauded the program’s flexibility, while urging CMS to encourage applications for physician-led bundling initiatives and offer technical guidance to physicians who are new to bundled payment models.

The American Hospital Association (AHA) has said it is still assessing the anticipated impact of the program on its members and determining which hospitals might prefer to participate.

The initiative is to take effect beginning in January 2013. To apply to participate in the program, providers must submit a letter of intent for Model 1 by September 22 and for Models 2-4 by November 4.

National Institute of Nursing Research Holds Conference to Set Priorities for End-Of-Life Care Research

On August 10-12, researchers, policy analysts, palliative and end-of-life care professionals and others gathered in Bethesda, MD for the National Institute of Nursing Research (NINR) “Science of Compassion” Summit, where participants reviewed existing end-of-life and palliative care policy, practice and research; discussed priorities for future research; and proposed solutions for access to end-of-life care challenges for patients.

For years, the NINR has led the National Institute of Health’s (NIH) end-of-life research, due in part to nurses often having the most direct contact with patients and their families. In recent months, palliative care has received increased attention as the government and health care stakeholders aim to improve care efficiency and quality for chronically and terminally ill patients while also controlling health care spending.

In 2009, Rep. Earl Blumenauer (D-OR) introduced legislation that would have allowed for Medicare coverage of end-of-life planning between patients and their health care providers, thus helping physicians address important questions with patients and more effectively deliver care in line with their wishes.

Originally included as part of the health care reform bill, the proposal was ultimately removed from the legislation after some politicians wrongly characterized the provision as a “death panel” that would lead to government-encouraged euthanasia for seniors.

The NINR is striving to develop ways to better include patients and their families in their own health care decision-making, based on research findings that there is often a wide gap between the more aggressive treatments that providers are accustomed to providing and the more minimalist approach that many patients and family members prefer.

Additionally, research has shown that effective communication between patients, family members and caregivers often results in a less stressful environment and higher satisfaction with patient care.

Sponsors of the “Science of Compassion” summit included the National Center for Complementary and Alternative Medicine, the National Institute on Aging, the NIH Clinical Center Department of Bioethics, the NIH Office of Rare Diseases Research, and the NIH Office of Research on Women’s Health.

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