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December 29, 2008

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave. SW
Washington, DC 20201

**RE: CMS-1404-FC: (Medicare Program; Changes to the
Hospital Outpatient Prospective Payment System and CY 2009
Payment Rates)**

Dear Acting Administrator Weems,

On behalf of the Association of Community Cancer Centers (ACCC), we appreciate this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) final rule with comment period regarding revisions to the hospital outpatient prospective payment system (OPPS), published in the Federal Register on November 18, 2008 (the "Final Rule").¹

ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC's more than 650 member institutions and organizations treat 45 percent of all U.S. cancer patients. Combined with our physician membership, ACCC represents the facilities and providers responsible for treating over 60 percent of all U.S. cancer patients.

ACCC is committed to ensuring that cancer patients have access to the entire continuum of quality cancer care, including access to the most appropriate cancer therapies in the most appropriate settings.

Hospital outpatient departments are a crucial part of the cancer care delivery system, providing a significant portion of this country's cancer care. Because advanced cancer treatments often are associated with considerable risk, several are available only through hospital-based oncologists, nurses, and pharmacists.

¹ 73 Fed. Reg. 68502 (Nov. 18, 2008).

Patients receiving these treatments must have substantial on-site clinical support in case of adverse reactions. ACCC members often serve patients who have numerous complications or histories of infusion reactions. In addition, some treatments, such as those involving radiopharmaceuticals, are available only in hospitals because they require specialized equipment and handling that is only available in that setting. Finally, hospital outpatient departments play an important role in the early adoption of new technologies and frequently serve patients who have recently completed participation in clinical trials.

In our comments on the Final Rule, ACCC would like to address three areas of particular concern for our membership: 1) reimbursement for separately paid drugs;² 2) reimbursement for pharmacy services and overhead; and 3) inclusion of data from 340B hospitals in OPSS rate-setting calculations. In the section on 340B hospitals, we respond to the nine questions CMS asked in the Final Rule with information provided by a sample of ACCC member hospitals from across the United States.

I. Reimbursement for Separately Paid Drugs without Pass-Through Status

In the Final Rule, CMS states that according to its analysis of claims data, the appropriate reimbursement level for drug acquisition costs and related pharmacy overhead costs of separately paid drugs without pass-through status is equal to average sales price (ASP) plus two percent.³ In order to provide a gradual change to a refined claims-based payment system, CMS implemented a reimbursement rate of ASP plus four percent instead of ASP plus two percent.⁴ ACCC is gravely concerned over the reduction in reimbursement from ASP plus five percent in 2008 to ASP plus four percent in 2009 and the indication of future reductions in the following years. ACCC, along with the pharmacy stakeholder group, has commented on numerous occasions and testified before numerous Ambulatory Payment Classification (APC) Panel meetings that reimbursement at less than the physician office rate of ASP plus six percent is based on flawed calculations and could harm hospitals' ability to provide important cancer therapies. Chris Hogan and the Moran Company both have analyzed CMS's rate-setting methodology for separately paid drugs. These studies show that CMS's methodology is fundamentally flawed due to the effects of charge compression and the inclusion of claims data from 340B hospitals.

In light of all the data and analysis that stakeholders have provided to CMS, and in light of the recommendations from the APC Panel to continue to reimburse drugs at ASP plus five percent, ACCC is extremely disappointed by CMS's decision to reduce reimbursement for separately paid drugs to ASP plus four percent for 2009. We urge CMS to reconsider this decision.

² We use "drugs" to refer to both drugs and biologicals.

³ 73 Fed. Reg. at 68657.

⁴ Id. at 68658.

II. Reimbursement for Pharmacy Services and Overhead

In the Final Rule, CMS decided not to adapt the recommendation of its contractor, RTI, to create two cost centers for drugs charged to patients. CMS intended for these cost centers to help the agency collect data on hospitals' pharmacy overhead costs associated with different groups of drugs for use in future rate-setting. ACCC applauds the decision to not implement this change because the administrative burden on hospitals to report costs using these cost centers would have been incredibly great and the data collected likely would not be useful to CMS for at least two to three years. We also were skeptical that hospitals could report meaningful data without clear instructions from CMS.

ACCC is disappointed that CMS did not implement the pharmacy stakeholder proposal for 2009, however. After much work and careful consideration, ACCC truly feels that the stakeholder proposal is the best option to begin reimbursing hospitals appropriately for the costs of providing drugs safely. The proposal, which is budget neutral and is supported by the APC Panel and a number of stakeholders, would allow more appropriate payment for drug acquisition and pharmacy services costs immediately. CMS itself recognized that the stakeholder proposal "could potentially provide more accurate OPPS payment for drugs and biologicals in the future."⁵ We urge CMS to work with ACCC and the other stakeholders to include the stakeholder approach in the proposed rule and to implement it for 2010. So that CMS can benefit from early input from stakeholders and the APC Panel as it develops the rule for 2010, CMS should model the effects of the stakeholder proposal and any other models it is considering, including exclusion of data from 340B hospitals from rate-setting calculations, for the next meeting of the APC Panel.

III. Inclusion of Data from 340B Hospitals in OPPS Rate-Setting Calculations

In the Final Rule, CMS raises the issue of the inclusion of claims data from 340B hospitals in the calculations of drug reimbursement rates for all hospitals. In order to better understand the problem, CMS asked nine questions in the Final Rule.⁶ ACCC provides answers to these questions as well as comments on the broader issue of 340B hospitals and their inclusion in rate setting.

First, ACCC does not believe that there should be two separate reimbursement rates – one for 340B hospitals and one for non-340B hospitals. We believe that all hospitals should be paid at the same rates. We do believe that 340B drug acquisition data should not be included in the calculation of drug reimbursement rates under the OPPS, however, as sales under the 340B program are excluded from the calculation of ASP. To include data from 340B hospitals, as CMS currently does, unfairly penalizes non-340B hospitals by artificially lowering drug reimbursement rates. A study by Chris Hogan found that when 340B pricing is taken out of the calculation for drug reimbursement rates, the mean cost as a percentage of ASP increases to ASP

⁵ Id. at 68652.

⁶ Id. at 68655.

plus 7.6 percent. Given this result, along with the effects of charge compression on CMS's estimations of drug costs, ACCC believes that CMS's calculations do not accurately reflect hospitals' drug acquisition and pharmacy overhead costs. CMS can take a significant step toward more accurate reimbursement rates by removing data from 340B hospitals from its calculations.

ACCC must stress however, that we do not want to increase reimbursement for one type of hospital at the expense of another. Although we do support removing the 340B hospital acquisition data from the rate-setting calculation, we do not believe that 340B hospitals should be paid at a different, lower rate. The 340B program was created to help hospitals that treat a disproportionate share of indigent patients. Congress intended for savings from the program to help participating entities "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."⁷ The Health Resources and Services Administration (HRSA) has informed hospitals that they may use savings from participation in the program to "invest in more services for patients"⁸ and that participating entities are not required to pass on the discounts from purchasing drugs at 340B prices to patients.⁹

To reduce the reimbursement to these hospitals would be inconsistent with the clear intent of Congress and HRSA for participating hospitals to use savings to expand care for their patients. It also would be unfair to those patients, who might see reductions in services available from safety net hospitals if reimbursement is reduced. In fact, many 340B hospitals already operate on significantly smaller margins than other hospitals,¹⁰ and further reductions in reimbursement would only harm their ability to serve at-risk populations. At the same time, it was never the intent of the program to penalize non-340B hospitals, which the current CMS methodology is effectively doing.

Our answers to each of the questions posed by CMS are below. These answers reflect responses from member hospitals in the south, mid-Atlantic, northwest, and southwest regions of the country and include academic and non-academic facilities.

- (1) Whether all HOPDs from a participating provider furnish drugs purchased under the 340B pricing program or only a subset of departments.

Our member hospitals tell us they furnish drugs purchased under the 340B program in only a subset of departments.

- (2) Whether all drugs are available to participating hospitals under the 340B program.

⁷ H.R. Rep. No. 102-384, pt. 2, at 12 (1992).

⁸ Elizabeth M. Duke, HRSA Administrator, Remarks to the Primary Health Care All-Grantee Meeting, June 22, 2005, <http://newsroom.hrsa.gov/speeches/2005/BPHC-June.htm>.

⁹ See, e.g., The 340B Drug Pricing Program: Your Guide to Participation, http://networkassist.ruralhealth.hrsa.gov/documents/20081119/340B_101_The_Basics_STANDARD_PPT1.ppt.

¹⁰ Obaid Zaman, et al., Health Care Safety Net Providers Face Significant Challenges, NAPH, June 2007, <http://www.naph.org/naph/AcademyHealth%20Char%20Poster%20final.pdf>.

Our members report that only drugs that are available in the outpatient setting are available under 340B pricing.

- (3) Whether hospital drugs provided to inpatients are purchased by hospitals at 340B program prices if the hospital is a participating provider.

Our members report that they do not purchase inpatient drugs at 340B program prices.

- (4) What proportion of a participating hospital's total costs and charges for drugs reflect drugs purchased through the 340B program.

Our members in the 340B program report that about 40 percent to 60 percent of the drugs they furnish are purchased at 340B pricing.

- (5) Whether hospitals participating in the 340B program receive other manufacturer discounts that impact their final drug cost.

Our member hospitals tell us that the drugs purchased through non-340B pricing typically are purchased through the hospital's Group Purchasing Organization (GPO), assuming that the hospital participates in a GPO.

- (6) Whether hospitals set different charges for drugs purchased through the 340B program than their charges for those same drugs purchased outside the program.

Our member hospitals report that they do not set different charges for drugs purchased through the 340B program.

- (7) The impact 340B drug purchasing agreements have on OPPS hospital claims data used to estimate drug costs.

As explained above, when 340B pricing is taken out of the calculation for drug reimbursement rates, the mean cost as a percentage of ASP increases to ASP plus 7.6 percent. This is an increase of 3.6 percentage points.

- (8) Whether hospitals participating in the 340B program should be paid for drugs under the OPPS at adjusted rates because they have different average hospital acquisition costs for drugs and biologicals from nonparticipating hospitals.

No. As discussed above, the intent of the 340B program is to help hospitals that serve a disproportionate share of indigent patients improve and expand care. Reducing reimbursement rates for these hospitals would limit their ability to use savings from the 340B program to support their mission. Therefore, these hospitals should not be reimbursed at lower rates than non-340B hospitals.

- (9) Whether we should use the equitable adjustment authority in section 1833(t)(2)(E) of the Act to adjust OPPS payments to hospitals for separately payable drugs based on hospitals' participation in the 340B program, so that drug payment for the two classes of hospitals (340B participating and 340B nonparticipating) would reflect the average drug acquisition and pharmacy overhead costs specific to each class of hospital.

No. For the reasons addressed above, we believe that CMS should not establish different payment rates for 340B and non-340B hospitals.

IV. Conclusion

ACCC appreciates the opportunity to comment on these important issues, and we encourage CMS to continue to work with us on them. It is imperative for the agency to fix the fundamental flaws in its rate-setting methodology for separately paid drugs in order for our members to continue to deliver high quality cancer care. We urge the agency to act now to ensure that payments for drug acquisition and pharmacy service costs are appropriate in 2010 and beyond. Removing 340B hospitals from the rate-setting calculation is just one improvement that needs to be made to CMS's methodology. Most important, the agency must correct for charge compression in order to reimburse hospitals appropriately for drugs and the pharmacy services associated with administering them safely. If you have any questions regarding any of the comments written here, please contact Matt Farber at (301) 984-9496 ext 221 or at mfarber@acc-cancer.org.

Sincerely,



Ernest R. Anderson, Jr., MS, RPh

President

Association of Community Cancer Centers (ACCC)