



A Passionate Voice for Compassionate Care

August 31, 2010

Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

REF: CMS-1504-P

RE: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2011 Payment Rates; Proposed Changes to Payments to Hospitals for Certain Inpatient Hospital Services and for Graduate Medical Education Costs; and Proposed Changes to Physician Self-Referral Rules and Related Changes to Provider Agreement Regulations

Proposed Rule

Dear Dr. Berwick:

The Catholic Health Association of the United States (CHA) is pleased to submit the following comments on the above notice of proposed rulemaking (NPRM), published in the *Federal Register* (Vol. 75 No. 148) on August 3, 2010.

1. Volatility of APC Relative Weights

As in past years, CHA continues to object to the year-to-year volatility of the ambulatory payment classification (APC) weights and urges the Centers for Medicare and Medicaid Services (CMS) to take appropriate steps to ensure stability in APC weights.

Similar to past years, the CY 2011 proposed rule includes significant swings in the ambulatory payment classification (APC) relative weights. For 25 APCs, the CY 2011 proposed weights decrease by 10 percent or more; for 13 of these, the reduction is greater than 20 percent and for 5 it is greater than 40 percent. In total, weights are lower for 152 APCs. On the other hand, weights increased for 267 APCs, going up at least 10 percent for 36 of them. For 13 APCs, the increase exceeds 20 percent and 5 APCs gain 40 percent or more. These comparisons are based

on 422 APCs and do not include drugs, biologicals and radiopharmaceuticals or new technology APCs. No comparison could be made for 3 APCs because they are new or lacked values 2011.

We continue to recommend as one approach to adjust medians derived from claims data to limit the amount of change that occurs from year-to-year. From the perspective of both hospital operations and payment policy, a stable payment environment is desirable. A stability policy should adjust the medians from claims data to ensure that no APC's median changes more than 5 percent compared to the medians used for payment in CY 2009.

2. ASC Quality Data Reporting

The proposed CY 2011 OPSS/ASC rule once again proposes to defer implementation of a quality data reporting program for ambulatory surgical centers (ASCs) and invites public comment on the deferral. **We agree that such deferral is appropriate.**

3. OPSS: Wage Index

CHA supports the use of the final FY 2011 version of the inpatient hospital prospective payment system (IPPS) wage index used to pay IPPS hospitals to adjust the CY 2011 OPSS payment rates and copayment amounts for geographic differences in labor cost for all providers that participate in the OPSS. This wage index was published as part of the FY 2011 IPPS final rule in the *Federal Register* on August 16, 2010.

CHA also supports the proposed adjustment of the FY 2011 wage index, as adopted on a calendar year basis for the OPSS, for all hospitals paid under the OPSS, including non-IPPS hospitals, located in a frontier State to 1.00 in instances where the assigned FY 2011 wage index for these hospitals is less than 1.00.

5. OPSS: Outlier Payments

CHA supports the proposal to increase the fixed-dollar outlier threshold for CY 2011 to \$2,025.00 in order to keep the outlier payment percentage to 1.0 percent of the estimated total OPSS/ASC payments.

6. Inpatient Only Procedures

CHA continues to urge the elimination of the inpatient list primarily because the list is not binding on physicians.

The list was created to identify procedures that are typically provided only in an inpatient setting and, therefore, would not be paid by Medicare under the hospital outpatient prospective payment system (OPSS). There are numerous problems created by the inpatient list as has been documented in past comments. The biggest continuing problem is that such a list is not binding on physicians. Consequently, since the physician receives payment when a procedure on the

inpatient list is performed on an outpatient basis, there is no incentive for the physician to be concerned whether Medicare will pay the hospital for the procedure. This is a particularly troubling issue in teaching hospitals. This fact underscores the reality that it is the physician, not the hospital, who determines whether a procedure will be performed in the outpatient or inpatient setting.

In the past, CMS has responded to such comments by saying that “[it] believes that appropriate education of physicians and other hospital staff by CMS, hospitals and organizations representing hospitals is the best way to minimize any existing confusion.” While such education is important, it alone will not solve the problem. When it comes to economic issues physicians, quite understandably, pay little attention to how hospitals are paid. The CMS provider education staff does not appear to have made any headway on this matter.

Should CMS decide to retain the inpatient list, we again urge the agency to consider developing an appeals process to address those circumstances in which payment for a service provided on an outpatient basis is denied because it is on the inpatient list. This would provide the hospital an opportunity to submit documentation to appeal the denial, such as physician’s intent, patient’s clinical condition, and the circumstances that allow this patient to be sent home safely without a more costly inpatient admission.

7. Physician Supervision.

Medicare Part B pays for hospital outpatient diagnostic and therapeutic services only when they are furnished under the appropriate level of physician supervision specified by CMS. In the CY 2009 OPPTS/ASC proposed and final rules with comment period, CMS provided a “restatement and clarification” of the requirements for physician supervision of hospital outpatient diagnostic and therapeutic services that had been initially set forth in the April 2000 OPPTS final rule with comment period. CMS received and responded to many comments during the CY 2010 rulemaking process and subsequent to the publication of the CY 2010 OPPTS/ASC final rule has continued to receive additional questions and expressions of concern about the direct physician supervision policy from hospitals and other stakeholders, including substantial comments from the CAH community made in response to the technical correction codifying the policy that CAHs are subject to the supervision policy for payment for therapeutic services. The larger hospital community continues to prefer lower levels of supervision for therapeutic services.

In the CY 2010 OPPTS/ASC proposed rule, CMS declined to withdraw the longstanding physician supervision policies for hospital outpatient services and went ahead with an effective date of January 1, 2009. In the CY 2010 OPPTS/ASC final rule with comment period, CMS did modify the physician supervision policy in three areas: two impacting therapeutic supervision and one impacting diagnostic supervision.

While CHA appreciates the policy changes CMS implemented in the CY 2010 OPPTS/ASC final rule, we continue to object to the CY 2009 “restatement and clarification” of the

requirements for physician supervision of hospital outpatient diagnostic and therapeutic services. We are particularly concerned about the impact of CMS' approach to direct supervision on small, rural and critical access hospitals (CAHs). Hospitals in rural communities have long functioned with lower levels of direct physician supervision of therapeutic services. Indeed, the Medicare conditions of participation only require that the physician or applicable NPP be available by phone at all times and that the physician or applicable NPP must be physically available on site within 30 minutes in cases of emergencies. Often, neither physicians nor NPPs are present in the CAH or small rural hospital when therapeutic services are furnished.

Rural communities face unique health care challenges, including significant shortages of physicians and non-physician professionals (NPPs). The lack of qualified personnel in rural areas makes it difficult to staff physicians or NPPs solely for supervision purposes. Services that extend after regular operating hours, such as observation services and services with significant monitoring components that are typically performed by nursing or other auxiliary staff, are of particular concern. While CMS has proposed a modicum of flexibility in this area, rural and critical access hospitals still face the likelihood of having to hire practitioners to do nothing but supervise outpatient services. While this would be burdensome for any hospital, it could be disastrous for those communities whose hospitals do not have the resources to hire or are not able to find physicians (or NPPs where allowed) able or willing to provide the level of supervision required by CMS and therefore are no longer able to provide patients will access to services such as chemotherapy or blood transfusion.

In recognition of the concerns of CAHs, CMS on March 15, 2010 decided it would not enforce these physician and NPPs supervision rules for outpatient CAH therapeutic procedures in 2010. **CHA strongly encourages CMS to reconsider its decision not exempt small rural hospitals and CAHs from the direct physician supervision rule. At the least, we urge CMS to extend the current moratorium with respect to CAHs. To allow sufficient time to complete and evaluate a study of the unintended consequences that may arise from the application of the new supervision rules for outpatient services provided by small and rural hospitals and CAHs.**

8. Cancer Hospitals

Under Medicare law, 11 cancer hospitals meeting the classification criteria are exempted from payment under the IPPS and are entitled to special hold harmless payments under the OPSS. Currently, a cancer hospital receives the full amount of the difference between payments for covered outpatient services under the OPSS and its Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) payment amount. Thus, cancer hospitals are permanently held harmless to their "pre-BBA" amount, and they receive transitional outpatient payments (TOPs) to ensure that they do not receive a payment that is lower under the OPSS than the payment they would have received before implementation of the OPSS. According to the proposed rule, CMS paid nearly \$164 million in 2009 in TOPs payments to these 11 hospitals.

CMS indicates that almost all of the 11 cancer hospitals receive TOPs each year; 10 of the 11 hospitals received the payments in 2009.

The Affordable Care Act (ACA) requires the Secretary to conduct a study to determine if, under the OPSS, outpatient costs incurred by cancer hospitals exceed the costs incurred by other hospitals. The law further requires that if the cancer hospitals' costs are determined to be greater than the costs of other hospitals paid under the OPSS, CMS shall provide for an appropriate adjustment to reflect those higher costs effective for services furnished on or after January 1, 2011. Such adjustments must be budget neutral.

The proposed rule notes that cancer hospitals remain eligible for TOPs payment (which are not budget neutral) and outlier payments (which are budget neutral).

Based on its findings from the required study, CMS proposes a hospital-specific payment adjustment determined as the percentage of additional payment needed to raise each cancer hospital's payment-to-cost ratio to the weighted average payment-to-cost ratio for all other hospitals paid under OPSS in the CY 2011 dataset. This proposed methodology would result in aggregate percentage payment adjustments for the 11 cancer hospitals of 41.20%, ranging from 5.90% to 82.60% for individual hospitals.

CHA believes the adjustment proposed by CMS is not consistent with the Affordable Care Act (ACA) mandate, violates the statute and the intent of Congress that the adjustment be budget neutral, and increases the beneficiary coinsurance significantly for services performed at the cancer centers.

Not consistent with the ACA mandate. The ACA directs the Secretary to provide for an appropriate adjustment and provides authority for the Secretary to make "*other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals.*" CHA does not believe that the Secretary has proposed an *appropriate* adjustment nor do we believe that it would result in *equitable payments*. The ACA provision does not require that cancer hospitals have the same payment-to-cost ratio as all other hospitals, yet that is the policy that CMS has proposed. Rather, the ACA requires that an *appropriate* adjustment be made which requires adjustments necessary to ensure *equitable payments*. Contrary to the statute, CMS has proposed extraordinarily large adjustments amounting to an average increase in Medicare payments of more than 42% for 11 hospitals, as shown in the table above. At the same time, CMS has proposed a budget neutrality adjustment that would reduce payments to all other hospitals by 0.7%. CHA does not believe it is appropriate or equitable to propose such substantial increases for 11 hospitals at the expense of significantly lower payments to all other hospitals. We believe that CMS's proposal to make such adjustments based on an agency notion to equalize payment-to-cost ratios is arbitrary and not supported by the statute. CHA observes that many of its members' hospitals and many other hospitals across the country are significant providers of cancer care. In providing cancer care, these hospitals face the same cost challenges, especially the high cost of cancer drugs, as the 11 cancer hospitals and yet they would be harmed

by the CMS proposal. The proposed CMS adjustment is not appropriate or equitable, and it does not represent good public policy because it fails to balance the various factors affecting OPSS payments. We note that the ACA gives CMS considerable discretion to determine the nature of the adjustment.

Violates the statute and the intent of Congress. The CMS proposal would reduce Medicare spending by about \$164 million in violation of the statutory requirement that the policy be budget neutral. This result occurs because CMS disregards the TOPs in its proposed adjustment. In fact, most of the approximately \$245 million that would be paid to the 11 hospitals under the proposed adjustment is offset by the reduction in their TOPs. The net gain to the 11 hospitals is only about \$80 million, while other hospitals lose \$245 million and Medicare OPSS spending falls by \$164 million *annually*. In its official estimate of the health reform law, the Congressional Budget Office did not score a savings for the ACA provision, yet it would save more than \$1.6 billion over 10 years under the policy proposed by CMS. The CMS proposal is a flagrant violation of congressional intent.

Increases the beneficiary coinsurance significantly for all services performed at the 11 cancer centers. The CMS proposal would significantly increase the beneficiary coinsurance for all OPSS services provided in the 11 cancer centers. The cancer center adjustment proposed by CMS is a hospital-specific adjustment, resulting in a range of beneficiary coinsurance increases from 5.9% to 82.6% by hospital. These are large and unnecessary increases in the beneficiary coinsurance and could cause hardship to Medicare patients.

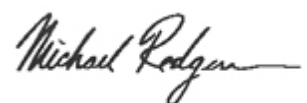
While CHA supports cancer hospitals and their mission, for the reasons given above we believe CMS's proposal is ill-advised and most oppose it. We have serious concerns about the impact of the reductions to all other hospitals as a result of the proposed budget neutrality adjustment. CHA believes that to the extent that CMS finalizes some adjustment for the cancer hospitals, it should satisfy two conditions. First, the amount of the additional payment should be determined in consideration of the TOPs to which the hospital already is entitled. Second, the policy should be truly budget neutral and not produce Medicare savings, as consistent with the statute and congressional intent.

9. Proposed Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable and Packaged Drugs and Biologicals.

CHA would like to commend CMS for the agency's proposal to increase payments for SCODs and other separately payable and packaged drugs and biologicals from ASP+4 to the comparable physician office rate of ASP+6.

In closing, thank you for the opportunity to comment on the proposed CY 2011 OPSS/ASC rule. We look forward to working with you on these and other issues to strengthen our nation's hospitals and improve the health of the patients they serve.

Sincerely,

A handwritten signature in black ink that reads "Michael Rodgers". The signature is written in a cursive style with a long horizontal flourish at the end.

Michael Rodgers
Senior Vice President
Public Policy and Advocacy