

SPECIAL BULLETIN

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CMS RELEASES FINAL RULES FOR CY 2011 HOSPITAL OUTPATIENT/ASC PAYMENT SYSTEM, PHYSICIAN FEE SCHEDULE AND HOME HEALTH PAYMENT SYSTEM

Includes ACA changes to GME and physician self-referral

The Centers for Medicare & Medicaid Services (CMS) on November 2 released three final rules for calendar year (CY) 2011 – the outpatient prospective payment system (PPS) and ambulatory surgical center (ASC) rule, the Medicare Physician Fee Schedule (PFS) rule and the Home Health PPS rule. Summaries of all three rules follow.

HIGHLIGHTS OF THE OUTPATIENT PPS/ASC RULE

The outpatient PPS rule reflects many of the AHA's key recommendations, including extending the enforcement moratorium by a year for critical access hospitals (CAHs) and other small, rural hospitals, establishing an advisory panel to help provide annual guidance to hospitals on how services need to be supervised and revising the outdated definition of direct supervision. We look forward to working with CMS to continue to update and refine the policy so that patients and communities have access to safe and high-quality services.

Payment Update: The rule includes a mandated 0.25 percentage point reduction to the CY 2011 marketbasket update of 2.6 percent, resulting in a marketbasket update for CY 2011 of 2.35 percent. The update in 2011 for hospitals that do not meet quality reporting requirements will be 0.35 percent. CMS projects that total payment for services furnished in hospital outpatient departments will be approximately \$39 billion in 2011.

Physician Supervision: CMS makes a number of changes to its policy in response to concerns and recommendations voiced by the AHA and others. First, CMS extends for an additional year – through CY 2011 – its decision not to enforce the direct supervision policy for therapeutic services provided in CAHs. Further, the agency is expanding this enforcement moratorium to include small and rural hospitals with 100 or fewer beds. CMS will consider hospitals to be rural if they are either geographically located in a rural area or are paid through the outpatient PPS with a wage index for a rural area.

CMS also finalizes its proposal to permit a two-tiered approach to supervision for a few specified hospital outpatient therapeutic services. CMS identifies a set of 16 "nonsurgical extended duration therapeutic services" to which this revised policy will



apply, including observation services, various intravenous and subcutaneous infusions and various therapeutic, prophylactic or diagnostic injections. These are procedures with a significant monitoring component that can take a long time, are not surgical and typically have a low risk of complication. For these services, CMS will require direct supervision only for the initiation of these services. Once the supervising physician or non-physician practitioner (NPP) deems the patient medically stable, the remainder of the service requires only general supervision. CMS adopts the same definition of "general supervision" currently used for certain diagnostic services. CMS requires that the transition from direct to general supervision be documented in the progress notes or in the patient's medical record.

CMS also revises the definition of direct supervision for all hospital outpatient services, to remove all references to the physical location of the supervising professional. That is, the definition of "direct supervision" will no longer require that the supervising professional be present on the hospital's campus for services furnished in the hospital or on its main campus, or in the provider-based department for services furnished in off-campus departments. Instead, the definition only requires that the supervising professional be "immediately available." This revised definition of direct supervision will also apply to those outpatient diagnostic services that require direct supervision.

Finally, consistent with the AHA's recommendations, CMS commits to establish through future rulemaking a process under which an independent technical committee made up of a diverse range of providers, including rural providers, will annually consider stakeholder requests to assign a level of supervision other than direct supervision for specific outpatient therapeutic services. CMS suggests that the Advisory Panel on APC Groups serve this function.

Quality Reporting:

- 2011 No new measures were added for 2011. Hospitals must continue to report on the 11 outpatient quality measures finalized in last year's final rule. These existing measures include five heart attack care measures for transfer patients, two surgical care measures and four measures of imaging efficiency. Hospitals that fail to meet the outpatient reporting requirements will receive a 2 percent reduction in their payment update.
- 2012 and beyond Similar to the inpatient PPS rule, CMS finalized the addition
 of quality measures over a multi-year period. For 2012, CMS finalized four new
 quality measures, including three measures of imaging efficiency and one
 structural measure assessing hospitals' use of laboratory data within their
 electronic health records, for a total of 15 measures. For 2013, CMS finalized
 eight additional quality measures for a total of 23 measures. Although CMS had
 proposed additional quality measures to be added in 2014, it did not finalize the
 measures in this rule but instead intends to refine the measures and propose



them again next year. CMS did not finalize its proposal to require hospitals to submit their measure population and sample size data.

The rule finalizes a data validation process that will begin in 2012 and is similar to the process implemented under the inpatient PPS. Under the new process, CMS will review approximately 50 medical charts from 800 randomly selected hospitals each year. The review will assess the accuracy of the hospital's measure rate, as opposed to the accuracy of individual data elements.

Hold-harmless Payments and Adjustment for Rural Sole Community Hospitals:

As required by law, the agency will no longer provide hold-harmless outpatient payments to sole community hospitals (SCHs) or other rural hospitals with 100 or fewer beds. CMS will continue, however, to apply a 7.1 percent payment increase for most rural SCH services and procedures paid under the outpatient PPS. As part of its fall advocacy agenda, the AHA will press the lame-duck Congress to extend the outpatient hold harmless policy and a number of other measures of importance to rural and other hospitals that have already expired or are set to expire at the end of this year.

Cancer Hospital Adjustment: CMS withdraws its proposal to increase each of the 11 "exempt" cancer hospitals' outpatient PPS payments by the percentage difference between their individual payment-to-cost ratio (PCR) and the weighted average PCR of the other hospitals paid under the outpatient PPS. While this adjustment would have increased outpatient PPS payments to cancer hospitals by an average of 41.2 percent for 2011, due to budget neutrality requirements mandated by the *Patient Protection and Affordable Care Act* (ACA), this adjustment would have reduced payment to all other hospitals by 0.7 percent. CMS states that it is withdrawing its proposal for a cancer hospital adjustment in order to study and deliberate upon the issues and concerns raised by commenters, including the AHA.

Drugs: CMS raises the drug packaging threshold from \$65 to \$70 for 2011. That is, drugs that cost more than \$70 per day are paid separately under their own ambulatory payment classification (APC), while drugs with per day costs below this threshold amount are packaged into the procedural APC with which they are billed. Further, CMS will pay for separately payable drugs and biologicals at the rate of average sales price (ASP) plus 5 percent in 2011– an increase from the 2010 rate of ASP plus 4 percent, but a reduction from the ASP plus 6 percent rate CMS proposed for CY 2011. This rate is intended to include drugs' acquisition and pharmacy overhead costs.

Outliers: CMS lowers the fixed-dollar threshold for outliers in 2011 to \$2,025, \$150 less than in 2010.

Partial Hospitalization Program Services: CMS finalizes its proposal, with modifications, to establish four separate APCs to be used to pay for Medicare partial hospitalization program (PHP) services, including two APCs for services furnished in



community mental health centers (CMHC), and two APCs for services furnished in hospital-based PHPs.

For 2011, the per-day payment rates for hospital-based Level I (days with three services) and Level II (days with four or more services) PHP services will be calculated using only hospital data. Hospitals will experience significant increases in PHP payments, with a 2011 rate of \$204 for Level I hospital PHP services (\$54 more than in 2010) and a 2011 rate of \$238 for Level II hospital PHP services (\$27 more than in 2010).

However, CMS revises its proposal to base payments for the CMHC-based PHP Level I and Level II services only on CMHC data in 2011. In response to concerns raised by the AHA and others that a precipitous reduction in payments for CMHCs in a single year could result in many of these organizations going out of business, with potentially substantial and serious consequences for hospitals and for Medicare beneficiaries requiring partial hospitalization services, CMS will mitigate the proposed rate reduction by instituting a two-year transition to CMHC rates based solely on CMHC data.

Preventive Services: As required by the ACA, CMS waives beneficiary cost-sharing for most Medicare-covered preventive services, including the initial preventive physical examination (known as the "Welcome to Medicare Visit") and the personalized prevention plan services (known as the "Annual Wellness Visit"). This waiver applies not only to the 20 percent coinsurance for the physician service, but also to any cost-sharing related to the separate facility payment when the service is furnished in a hospital outpatient department, as well as to those preventive services, such as colonoscopies, that may be furnished in an ASC. The ACA also requires that the Annual Wellness Visit be excluded from payment under the outpatient PPS. Instead, if the service is furnished in the hospital outpatient department, payment may only be made to the hospital by submitting a claim under the Medicare physician fee schedule. Finally, CMS waives the Part B deductible for colorectal cancer screening tests that become diagnostic, including all surgical services furnished on the same date as a planned colorectal cancer screening test.

Cardiac and Pulmonary Rehabilitation: CMS clarifies that a CAH outpatient department is considered a covered setting for cardiac, pulmonary and intensive cardiac rehabilitation programs, provided that the program meets all of the regulatory requirements including direct supervision of all services by a physician.

Wage Index Floor for Frontier States: The rule implements an ACA requirement to establish a wage index floor of 1.0 for Medicare inpatient and outpatient PPS payments to hospitals in frontier states. CMS uses Census Bureau data to establish the following states as eligible: Montana, Nevada, North Dakota, South Dakota and Wyoming.



ASCs: In 2011, CMS completes its four-year transition to the outpatient PPS-based payment system for ASCs. In 2011, CMS will pay for most ASC services at 100 percent of the 2011 fully implemented ASC amount, rather than using a transitional blended rate.

The ACA requires that for 2011 CMS must update the ASC payments by the percentage increase in the Consumer Price Index for All Urban Consumers (estimated at 1.5 percent) reduced by a productivity adjustment (estimated at 1.3 percent), resulting in an inflation update of 0.2 percent.

The final rule also adds six surgical procedures to the list of allowed ASC procedures and, consistent with policies for the outpatient PPS, updates the list of device-intensive procedures and covered ancillary services and their rates.

Graduate Medical Education (GME): The outpatient PPS/ASC final rule implements several provisions enacted by the ACA, including inpatient policy related to payments for direct graduate medical education (DGME) and indirect medical education (IME).

- Redistribution of unused residency positions As required by law, for cost-reporting periods beginning on or after July 1, 2011, hospitals will lose 65 percent of their unused or unfilled residency positions and qualifying hospitals will be able to request up to 75 new positions. In general, CMS adopts as final its proposed procedures for determining whether, and by what amount, a hospital's full-time equivalent (FTE) resident cap is subject to a reduction. However, the agency makes significant modifications to the specific criteria and process it will use to determine whether hospitals will receive an increase in their resident caps. Specifically, among other changes, CMS extends the application deadline to January 21, 2011 (from December 1, 2010); modifies its priority categories and ranking criteria; and clarifies that a hospital may not request additional cap slots solely because it is training residents above its current cap but rather it must increase the overall number of residents being trained.
- Counting resident time in non-provider settings As required by the ACA, CMS
 is eliminating the requirement for hospitals to incur "all or substantially all" of the
 costs for training residents in a non-hospital setting. Instead, hospitals must
 incur only the costs of the salaries and fringe benefits of residents training in nonhospital sites, as well as track resident time in non-hospital sites, to count this
 time for DGME and IME payment. In general, CMS adopts as final its proposed
 policies related to this recordkeeping requirement.
- Counting resident time for didactic and scholarly activities The ACA made several changes to the counting of resident training time for didactic, scholarly and other activities. In the outpatient PPS/ASC rule, CMS implements these changes, including allowing: 1) IME payment for certain non-patient care



activities in hospital settings, including didactic conferences and seminars; 2) DGME payment for certain non-patient care activities in non-hospital settings, including didactic conferences and seminars but not research that is not associated with the treatment of a particular patient; and 3) IME and DGME payment for the time spent by residents on vacation, sick leave and other approved leave, as long as the resident's leave time does not extend the program's duration. In general, CMS adopts as final its proposals related to the implementation of these policies.

Resident cap positions from closed hospitals – As required by law, CMS adopts a process that redistributes residency slots from teaching hospitals that close on or after March 23, 2008 to other area hospitals, so that when teaching hospitals close, their FTE resident cap slots will not be eliminated. In the final rule, CMS lists the number of slots available for redistribution based on hospital closures between March 23, 2008 and August 3, 2010, makes modifications to its ranking criteria, and extends the deadline to apply for these slots to April 1, 2011 (from January 1).

Physician Self-referral: CMS finalizes most of the AHA-supported changes required by the ACA that narrow the "whole hospital" and "rural provider" exceptions in the physician self-referral law by prohibiting their use by new physician-owned hospitals and limiting the ability of existing physician-owned hospitals to expand their capacity. Additional provisions affecting existing physician-owned hospitals are aimed at preventing conflicts of interest, ensuring that all ownership and investment interests are bona fide, and promoting patient safety. The rule clarifies the interaction of various effective dates within the self-referral provisions, especially with respect to which facilities qualify as grandfathered existing facilities, setting the baselines for limitations on aggregate physician ownership and future growth, and how current construction projects will be handled (both expansions of existing and new physician-owned hospitals).

HIGHLIGHTS OF THE MEDICARE PHYSICIAN FEE SCHEDULE RULE

Payment Update: The rule implements a 24.9 reduction to Medicare physician payments beginning January 1. The *Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010* had delayed the 2010 cut in physician payments and provided a 2.2 percent update in payments from June 1 through November 30. Beginning December 1, payments will decline approximately 23 percent, with an additional 2 percent decline in January. Cuts of this magnitude are unsustainable; the AHA will urge Congress to permanently fix the flawed physician payment formula.

Multiple Procedure Payment Reduction (MPPR) for Therapy Services: The rule implements a 25 percent (down from a proposed 50 percent) MPPR for outpatient therapy services, resulting in a payment cut of approximately 7 percent in 2011 to



hospital outpatient therapy services. Specifically, beginning January 1, CMS will make full payment for the "always therapy" service with the highest practice expense (PE) value but then will apply a 25 percent reduction to the PE component for any second or subsequent therapy service provided to the same patient on the same day. While CMS responded to the AHA's concerns by mitigating the reduction, we remain extremely disappointed that the agency chose to implement a flawed policy that will result in significant cuts to hospitals for these important services.

Incentive Payment for Primary Care Services: As required by the ACA, the rule implements a 10 percent primary care incentive payment (PCIP) for primary care services delivered by a primary care practitioner for five years, beginning January 1. Under the final rule, qualifying practitioners are primary care physicians in the specialties of family medicine, internal medicine, geriatric medicine and pediatric medicine, as well as nurse practitioners, clinical nurse specialists and physician assistants, for whom primary care services accounted for at least 60 percent of the practitioner's Medicare PFS allowed charges.

Incentive Payment for General Surgery Services in Health Professional Shortage Areas (HPSAs): Also beginning January 1, the rule implements the ACA provision providing a 10 percent surgical incentive payment for general surgeons performing major surgical procedures in a zip code located in a HPSA.

Deductible and Coinsurance for Preventive Services: As required by the ACA, the rule eliminates cost-sharing requirements including beneficiary co-payments and deductibles for preventive screenings and services receiving a recommendation of "A" or "B" by the U.S. Preventive Services Task Force beginning January 1. The law also eliminates the Medicare Part B deductible for all colorectal cancer screenings, regardless of coding, subsequent diagnosis and ancillary tissue removal during screening.

Annual Wellness Visit and Personalized Prevention Plan: In addition to the onetime "Welcome to Medicare" comprehensive physical exam, the rule adopts the ACA policy providing Medicare beneficiaries with annual wellness visits, including "personalized prevention plan services," with zero cost-sharing, effective January 1.

Permitting Physician Assistants to Order Post-Hospital Extended Care Services: Effective January 1, the rule implements the ACA provision that adds physician assistants to the list of "physician extenders" that can perform the initial certification and periodic recertifications required to order skilled-nursing facility level care.

Improved Access for Certified Nurse Midwife Services: Beginning January 1, the rule increases reimbursement for certified nurse-midwives' services to 100 percent of the PFS amount paid to physicians.



Clinical Laboratory Fee Schedule (CLFS) – Signature on Requisition: CMS finalizes its proposed policy to require a physician's or NPP's signature on requisitions for clinical diagnostic laboratory tests paid under the CLFS. This policy does not affect physicians or NPPs who choose not to use requisitions to request lab tests. Such physicians or NPPs can continue to request such tests by other means, such as by using annotated medical records, documented telephonic requests or electronically.

HIGHLIGHTS OF THE HOME HEALTH PPS RULE

Payment Update: The rule includes an overall payment cut of 4.89 percent, which exceeds the cut initially proposed and lowers Medicare payments by \$960 million from 2010 levels. This cut includes, among other adjustments, a 1.1 percent marketbasket update and the proposed -3.79 percent coding offset. CMS did not finalize a coding offset for CY 2012, as proposed.

Add-on Payment: As mandated by the ACA, the rule reinstates the former 3 percent payment add-on for home health services furnished in a rural area on or after April 1, 2010 and before January 1, 2016.

Outliers: In response to the ACA, CMS finalizes two outlier provisions: 1) a 10 percent **facility** cap on outlier payments; and 2) a 5.0 percent outlier pool combined with a 2.5 cap on **overall** outlier payments, which in effect is a 2.5 percent reduction in overall Medicare payments.

Face-to-Face Encounter: CMS finalizes its proposal for hospital-based home health agencies that mandates a face-to-face encounter between the physician or non-physician practitioner and the beneficiary. In the final rule, CMS expanded the window of time for this encounter from 30 days to between 90 days before the start of care and 30 days after care begins. Also, CMS will allow a hospitalist to perform the encounter even if a community-based physician manages a beneficiary's home health services and certifies the patient's care plan.

NEXT STEPS

The outpatient PPS/ASC final rule, available at <u>http://www.cms.gov/HospitalOutpatientPPS/HORD/list.asp#TopOfPage</u>, will be published in the November 24 *Federal Register*. The PFS rule, available at <u>http://www.ofr.gov/inspection.aspx</u>, will be published in the November 29 *Federal Register*. The Home Health PPS rule, available at <u>http://www.ofr.gov/OFRUpload/OFRData/2010-27778_PI.pdf</u>, will be published in the November 17 *Federal Register*. All three rules take effect January 1.

Watch for AHA Regulatory Advisories with further details in the coming weeks.