CALIFORNIA
HOSPITAL
ASSOCIATION

Providing Leadership in Health Policy and Advocacy

September 14, 2007

Mr. Kerry N. Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphery Building, Room 445-G
200 Independence Ave. SW
Washington, DC. 20201

Dear Mr. Weems:

RE: CMS 1392-P, Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Medicare and Medicaid Programs: Proposed Changes to Hospital Conditions of Participation; Proposed Changes Affecting Necessary Provider Designations of Critical Access Hospitals

On behalf of the California Hospital Association, thank you for the opportunity to comment on the Outpatient Prospective Payment System (OPPS) proposed rule for calendar year 2008 (CY2008). The California Hospital Association (CHA) is a nonprofit organization dedicated to representing the interests of hospitals and health systems in California. CHA represents more than 400 hospital and health system members, including general acute care hospitals, children's hospitals, rural hospitals, psychiatric hospitals, academic medical centers, county hospitals, investor-owned hospitals, and multi-hospital health systems. These hospitals furnish vital health care services to millions of our states' citizens. CHA also represents more than 100 affiliate, associate, and personal members. CHA provides its members with state and federal representation in the legislative, judicial, and regulatory arenas, in an effort to improve health care quality, access and coverage; promote health care reform and integration; achieve adequate health care funding; improve and update laws and regulations; and maintain public trust in health care.

In addition to these comments, we support the comments and recommendations of the American Hospital Association (AHA).

1215 K Street, Suite 800, Sacramento, CA 95814 · *Telephone:* 916.443.7401 · *Facsimile:* 916.552.7596 · www.calhospital.org
Corporate Members: Hospital Council of Northern and Central California, Hospital Association of Southern California, and Hospital Association of San Diego and Imperial Counties

OPPS: PACKAGED SERVICES

In its written comments accompanying the proposed rule, CMS emphasizes the need for increased "packaging" of ancillary services, inexpensive drugs, medical supplies, implantable devices, and other ancillary services associated with a procedure into a single payment for the procedure. CMS states that increased use of "packaging," and further use of "bundling" services into a single course-of-care payment promotes provider efficiency while also stabilizing payment volatility through the law of averages.

For CY 2008, CMS proposes to package the following HCPCS codes into payment for the primary diagnostic or therapeutic modality to which it believes they are ancillary and supportive:

- Guidance services;
- Image processing services;
- Intraoperative services;
- Imaging supervision and interpretation services;
- Diagnostic radiopharmaceuticals;
- Contrast media; and,
- Observation services.

In prior rulemaking cycles, CHA has been supportive of increased outpatient PPS packaging, and remains generally supportive. However, we have reservations about packaging certain ancillary items and services, particularly where increased packaging may lead to poor adaptation of new technology, or may lead perversely to diminished use of more efficient treatment modalities. For the services that CMS proposes to package for the CY 2008 OPPS, we have particular concern with packaging of observation services. Based on our analysis, which is discussed in greater detail below, CHA opposes packaging outpatient services until more is known about the impact packaging would have on the provision of this important modality.

OPPS: OBSERVATION SERVICES

Observation units, which are sometimes referred to as clinical decision units (CDUs), are an increasingly important area that exist in some hospitals which allow for monitoring "stable" emergency patients over a period of time before making a decision about whether or not to admit a patient to an inpatient unit. Over time, CDUs have proven their efficacy in diminishing hospital overcrowding while assuring continuity of care and, by substituting for inpatient short stays, lowered costs to the Medicare program. However, in spite of several recommendations on the part of the APC panel and various stakeholder groups, CMS has not expanded the list of diagnoses for which observation services are payable beyond asthma, chest pain, and congestive heart failure. In the CY 2008 OPPS rule, CMS proposes to expand packaging to include observation services into the primary APC to which it is ancillary, which would, CMS believes, effectively expand the number of diagnoses for which observation services would be payable.

Packaging Observation Services May Artificially Diminish Payment

CHA believes that packaging observation services may have the untoward effect of discouraging CDU development. While observation services are separately payable, hospitals have a clear incentive to code to utilize observation when it is clinically indicated and reimbursable under present regulation, because if the observation stay isn't coded for, the hospital cannot receive payment for the service. However, if the hospital receives no additional payment for observation services, and instead these payments are packaged in an APC for an ED stay, incentives to code for observation services will disappear. Because of declining documentation, the costs for observation services may be lost from hospitals' cost reports, thereby diminishing payment in the long run.

Packaging Observation Services May Discourage Further CDU Development

We believe that separate payment for observation services provide a tangible incentive for hospitals to consider making the capital and human resources investments necessary to open CDUs and, as the patient population becomes older and more medically needy, expand existing CDUs. According to the IOM, approximately 30 percent of hospitals are considering opening or have opened a CDU, which while encouraging, is likely far short of the number of hospitals with crowded emergency departments that could benefit from relief from overcrowding that a CDU can provide.

Were CMS to bundle observation services into a separately payable independent service relating to a disease or condition, the explicit incentive for establishing a CDU would be lost. We believe that this would lead to fewer hospitals considering establishing a CDU, and instead continuing to admit beneficiaries to inpatient beds, thereby doing nothing to mitigate ED overcrowding, and raising costs to the Medicare program.

Packaging Observation Services Harms Hospitals with Observation Services

Based on CHA analysis of claims data, we found that packaging observation services will redistribute outpatient dollars in such a way that hospitals which utilize observation beds and code appropriately will experience a net loss of revenue from the proposal, while hospitals who don't use observation services, or who don't code appropriately will realize gains. This analysis strongly suggests a perverse incentive, where hospitals who have established CDUs to, as the IOM states "...improve reduce boarding and diversion, avoid expensive hospitalization, and [sic] contribute improved management of common ambulatory-care sensitive conditions" are penalized by a net loss of CDU-related revenue.

While CHA supports CMS' goal of expanding the diagnoses for which observation services are payable, we believe that packaging this service into payment for other separately payable services would suppress hospitals' incentives to create new CDUs, and unfairly penalize those institutions who are currently using and coding appropriately for observation services. **We urge CMS to reconsider packaging observation services for CY 2008, and revisit the proposal when observation services become more widely adopted by the hospital community. For the interim, we strongly suggest that CMS continue paying separately for observation, but that it removes condition-specific criteria for payment, as per the IOM recommendation regarding CDUs.**

PROPOSED DEVELOPMENT OF COMPOSITE APCS

In the proposed rule, CMS proposes developing two "composite" APCs, which would be a single payment for a bundle of separately paid services performed in a single-day encounter or multi-day episode of care. Like "packaged" services above, the agency believes that these composite APCs will give hospitals greater incentives for efficient care.

As previously noted, CHA is generally supportive of increased use of packaging and bundling in the outpatient PPS, however CMS notes in the proposed rule that it requires input from providers about which services would be appropriate candidates for these schemes. We believe that CMS should continue to actively engage with the provider community and the APC Panel in further development of composite APCs, not only to discern which procedures are ancillary or supportive for purposes of packaging, or which major services can be bundled into a single course-of-care payment, but to evaluate whether untoward consequences may occur as the result of bundling and packaging (such as would happen were CMS to package observation services, we believe).

OPPS: PARTIAL HOSPITALIZATION

In prior rulemaking cycles, CMS expressed concern that it did not have sufficient evidence to support using the median per diem cost produced by the current year's data. In CY 2006, for example, CMS voiced its belief that cost report-based reduction to the per-diem for partial hospitalization programs (PHP) would drop the payment rate to below the cost of providing PHP services, and scaled back a derived 44 percent reduction to 15 percent. Unlike in other areas of the OPPS, where cost report data are derived solely from hospitals, data for community mental health centers (CMHCs) are used in the PHP cost analysis. For the past several years, CMS remarks that it has observed considerable volatility in CMHC data. In the CY 2008 proposed rule, the agency remarks, "CMS believes that some CMHCs have manipulated their charges in order to inappropriately receive outlier payments."

For CY 2008, in an effort to better understand PHP costs, CMS drilled down to the PHP unit of service level. Under CMS policy, all PHP programs must provide at least three units of service per day in order to properly bill Medicare for the per diem. However, CMS analysis indicates that 64 percent of CMHC PHP days were days where 3 or fewer services were provided, while 34 percent of days that hospitals were paid were days where 3 or fewer services were provided. CMS claims that per diem rates were predicated on a much higher assumption of service delivery, and so the agency proposes cutting the per diem for all settings from $233.37/day in CY 2007 to $178/day in CY 2008; this would represent a cut of approximately 24 percent to PHP services.

From conversations with members, CHA believes that these cuts would be devastating to beneficiaries' access to outpatient and community-based mental health services in California. In 2005 through 2006, CHA member institutions provided approximately 86 percent of all PHP

services. From our analysis of claims data from 2005 through 2006, we believe that California's PHP programs would experience a net loss of almost $27 million per year in lost Medicare revenue, of which $23.4 million would be directly attributable losses to CHA member institutions. Comments from the institutions providing PHP programs indicate that they presently find PHP administratively burdensome and costly to provide; many state that further cuts – especially cuts of this magnitude –would make PHP programs unsustainable, and thus would strongly consider terminating their PHP programs.

We would also like to illustrate the "ripple effect" cuts to PHP have on other outpatient mental health services. As CMS noted in the preamble to the proposed rule on composite APCs, it is a long standing CMS policy to limit the aggregate payment for less intensive mental health services furnished on the same date to the payment level for a day of partial hospitalization. A number of our member institutions provide less intensive mental health in the outpatient setting, which is paid on a per-unit basis until it reaches the PHP per diem payment cap. Several of these institutions have stated that they have chosen to provide outpatient mental health services in this manner rather than under the auspices of a PHP program because they find the administrative difficulties involved in running a PHP program to be more troubling than the potential economic gains that are lost through the PHP cap. Importantly, many of these members provide three or more units of service per beneficiary per day in treatment in their outpatient mental health (non-PHP) programs, and thus have non-PHP outpatient mental health programs that are very similar to PHP with respect to intensity and setting. For these providers, a cut to the PHP per diem, especially a cut as large as that which is proposed in the proposed rule, would diminish beneficiary access not only to PHP, but – due to the reduction of the PHP per diem payment cap - also to outpatient mental health services which are paid on a per unit of service basis.

Moreover, based on CMS' own data, there appears to be a substantial difference in PHP costs and service intensity between the hospital and the CMHC setting. With respect to service intensity, CMS analysis indicates hospital-based PHP programs tend to have a greater number of days where more than three units of service were performed, and that hospitals' per diem costs are higher than those of CMHCs, irrespective of the number of units of service performed. We also note that CMS' proposed $178 per diem is an amount equal to the agency's estimate of CMHC costs for all days, taking into account the lower volume of services delivered per day. CHA believes this payment to be completely inappropriate for hospitals, which tend to deliver a more intensive PHP level of care and who have higher per diem costs. CMS analysis of hospital-based PHP median per diem cost for days with four units of service or more (which occurs in the large majority of hospital-based PHP days) is $218 per day, which we believe is much closer to the cost of care provided in hospital-based PHP programs than the $178 proposed in the rule.

Finally, we wish to underscore that PHP care is intensive outpatient care which allows beneficiaries to remain in their community while receiving needed mental health care, an important aspect of community-based care models. PHP is widely regarded as a substitute to inpatient psychiatric hospitalization, which tends to be more expensive for Medicare and more disruptive to beneficiaries. Cuts to PHP, especially cuts of this magnitude have real potential to curtail provision of this much needed, cost effective, community based alternative to hospitalization. The proposed cuts would affect beneficiary access not just to PHP, but to other

outpatient mental health programs, and may prompt more inpatient hospitalization, thus increasing costs to the Medicare program. **CHA strongly opposes CMS' proposed cuts to PHP, and urges the agency to re-consider its ongoing rate cuts to ensure adequate beneficiary access to PHP services. Further, we suggest that CMS consider providing differential per diem payments based on the setting and intensity of services provided during the PHP day.**

OPPS: Specified Covered Outpatient Drugs

Pharmacy Overhead Costs

For the proposed rule, CMS rejects an APC Panel recommendation that would have implemented a three phase plan to address pharmacy costs in the OPPS. In the first phase, the APC Panel recommended that CMS establish a system of defining pharmacy overhead categories for outpatient drugs that require different levels of outpatient resources, and categorize the drug handling and administration resources required as low, medium, and high. Second, CMS would review outpatient pharmacy overhead estimates from GAO and MedPAC, and consider stakeholder survey data. Third, CMS would establish a mechanism whereby providers could bill pharmacy overhead costs on claims data, but using HCPCS codes that correspond with the aforementioned low/medium/high taxonomy. CMS ultimately rejects this recommendation as being inconsistent with the overall goal of increased bundling and packaging.

Rather, CMS proposes that providers remove the pharmacy overhead charge from the charge for the drug or biological and instead report the pharmacy overhead on an uncoded revenue code line on the claim. To aid in bundling, this policy would apply to all drugs and biologicals, irrespective of whether the drug or biological is packaged or separately payable. The exception to this proposed policy is radiopharmaceuticals, for which overhead and handling are reflected in charges.

CMS intends to use this policy as a transitional step towards greater bundling of part B pharmaceuticals. Once adequate data are collected, CMS indicates that it will package appropriate overhead for the drug or biological with the procedure or procedures to which they are most closely associated.

As stated previously, CHA is strongly in support of increased packaging and larger bundles of single payments in the OPPS. We believe that these payment reforms will lead to enhanced efficiency and less volatile pricing while simultaneously aligning incentives for appropriate care. However, we don't believe that CMS' transitional step of reporting the pharmacy overhead on an uncoded revenue code line on the claim is achievable by CY 2008. From conversations with our members, we believe that the administrative burden involved in re-pricing all part-B pharmaceuticals and biologicals cannot be reasonably accomplished in so short a time frame. Moreover, we believe that it would be exceedingly time-consuming to derive an allocation resource use on a per-drug basis.

CHA cannot support CMS' proposed rule change at this time. Rather, we suggest that CMS re-consider methods for developing median pharmacy overhead costs in like drugs, perhaps using the APC Panel's proposed taxonomy. CMS could then package median pharmacy overhead payments for administratively similar drugs into appropriate APCs without requiring hospitals to assume the enormous burden of re-pricing and developing drug and facility-specific resource utilization estimates for thousands of drugs in outpatient pharmacies.

OPPS: DEVICE-DEPENDENT APCS

Proposed Payment When Devices are replaced with Partial Credit to the Hospital
In the CY 2007 OPPS proposed rule, CMS promulgated a policy that reduces reimbursement for those APCs where the hospital is replacing a faulty device for a patient for whom the previous device has failed, and when the hospital receives full credit for the cost of the device from the manufacturer. Since 2007 however, the agency has received numerous question from provider groups regarding payment and reporting when the hospital replaces a device, but receives only partial credit to the manufacturer.

CMS now believes that hospitals should report occurrences of devices being replace under warranty or with partial credit granted to the hospital so that they may be able to identify systematic device problems and adjust claims accordingly. To do so, CMS proposes a HCPCS modifier for CY 2008 that would be reported in all cases where the hospital receives partial credit for a replaced device. Further, the agency proposes to reduce the payment of the APC into which the device cost is packaged by one half of the amount of the offset amount that would apply if the device were replaced at no cost (or with full credit) from the manufacturer. However, it would only do this in instances where the device credit is equal to or greater than 20 percent of the cost of the new replacement device

CMS states that it sets the threshold for reporting at 20 percent because if the agency were to take a 50 percent discount for replacement devices where the hospital received less than 20 percent of costs reimbursed by the manufacturer, it would be reimbursement that is "too low" for the cost of the replacement procedure. Further, the administrative burden in reporting discounts of less than 20 percent would outweigh the savings to the program.

CHA appreciates CMS' thoughtful approach to this problem. We agree that the administrative burden associated with reporting and changing reimbursement for devices where less than 20 percent of the cost of the device was credited to the hospital outweigh the savings to the program. However, we are concerned that CMS adjusting payment for the device portion of the APC by 50 percent in instances where the credit realized by the hospital may be more than twenty but less than 50 creates the problem of inadequate reimbursement for these devices.

With implantable devices in most hospitals, it is the physician who is performing the implantation procedure and not the hospital that chooses the implantable device. Moreover, we believe that it is not hospitals' role to assess the failure rates of implantable devices even in

instances where the hospital is empowered to make purchasing decisions regarding these devices. Ultimately, when implantable devices fail it is almost never the fault of the hospital OPD, who rarely make the purchasing decisions and who don't have the technical capacity to assess device failure. Yet the CMS proposal would force hospitals to absorb the difference between the discount offered by the manufacturer and the payment discount from CMS. **We believe this is unfair, and we oppose this aspect of the proposed rule. Rather, we suggest that the 20 percent threshold stay in place (for the reasons outlined in the proposed rule and above), but that CMS match the amount of the discount against to the payment adjustment.** In this manner, CMS should continue to realize savings to the program from devices replaced with partial credit to the hospital, but would not penalize hospitals unfairly for device failure that occurs at no fault to the OPD.

OPPS: QUALITY DATA

Reporting Hospital Outpatient Quality Data for Annual Payment Update
In the proposed rule, CMS responds to a 2006 congressional mandate to formulate measures for use in a hospital outpatient quality reporting program. Per congressional instructions, CMS must develop an array of hospital outpatient quality measures, that hospitals must report upon completely and adequately in order to receive a full market basket payment update. If the hospital is unable to comply, they will receive the market basket update minus 2 percent.

To formulate the quality reporting measures, CMS turned to the hospital quality alliance (HQA), and proposes to use ten measures that have received preliminary HQA approval as its OPPS measures for CY 2008. These measures include five relating to patients treated for myocardial infarction (MI, or heart attack) in the ED and then transferred to another facility for definitive care, four additional measures relating to physician care outside the ED, and Hemoglobin A1c levels, which CMS regards as an intermediate outcome measure.

Noticeably absent from the proposed rule, however, are any indications about how the measures would be implemented. We are particularly concerned about PRRI #1: Hemoglobin A1c (HbA1c) levels. While we recognize the important role that HbA1c plays in managing the care of the chronically ill diabetic, we believe that it is unnecessary to assess HbA1c in diabetics in all OPD encounters, and ask that CMS consider limiting reporting requirements under some circumstances. For example, an HbA1c may be unnecessary when a patient requires suture care for a simple laceration in the ED, though it may be more important when the patient is receiving multi-day outpatient therapy. Further, we suggest that this measure and several others in the proposed set for CY 2009 and beyond are measures principally related to ongoing or primary care. While CHA recognizes the validity of these measures for patients receiving ongoing ambulatory or extensive acute care, we question their utility in single encounter outpatient and minor procedural settings.

As CMS implements the OPD pay for quality reporting initiatives, we strongly suggest that the agency proceed cautiously and give careful consideration to a set of criteria that govern

what quality measures must be reported upon and in what circumstances, especially with regards to primary care-focused PQRI measures.

Timing and Implementation
As CMS implements the OPPS pay for quality reporting initiative, we note that it will require hospitals submit notice of participation by November 15th 2007. While this timeframe may allow for adequate time for hospitals to submit their applications, we have concerns that many hospitals will have sufficient time to purchase and install new systems to report on the OPD measures, and train OPD staff in time for a January 1' 2008 implementation. We are also concerned that CMS' requirement that hospitals submit their IPPS pay for quality reporting applications in August may create the perception that the necessary application has already been submitted, and hospitals may inadvertently miss the OPPS application deadline. Finally, we note that the proposed submission timeframe for the outpatient reporting program is 120 days, which is several days shorter than the 135 days required under the inpatient reporting program. We are concerned that differential submission timeframes will only exacerbate hospitals' confusion about this program, and we suggest that CMS use the 135 day reporting timeframe for both programs to alleviate the potential for missed submission deadlines due to confusion over the timeframe.

While we appreciate and support CMS' proposal that hospitals be considered "participating" until they notify the agency otherwise, in the future, we encourage CMS to consider a unified application and deadline, which would help mitigate administrative burden associated with duplicative data entry, and help to mitigate confusion around application timeframes and deadlines.

CHA is very concerned about CMS' proposed outpatient pay for quality reporting initiative as described in the proposed rule. The measures have not been field-tested, and one (HbA1c) appears to have only a tenuous relation to OPD quality for many outpatient procedures and care, especially for non life-threatening OPD ED visits, and minor procedures. Further, CMS' proposed timeframe is extremely short, and hospitals may find its application deadlines confusing. For these reasons, we urge CMS not to adopt the OPPS pay for quality reporting initiative in the final rule. Rather, we suggest that CMS utilize the ensuing year to address many of the details that were not included in the proposed rule, and re-propose outpatient quality reporting for CY 2009.

OPPS: HOSPITAL VISITS

Emergency Department Visits
CHA shares AHA's concern about CMS treatment of part A and part B ED visits, especially with respect to its payment policy for "fast track" areas of EDs. In general, fast track areas function as a low-acuity, high volume area of the ED that handles lower acuity complaints, thereby leaving the main corpus of the ED available for the badly ill and injured. Further, we note that the IOM, in its 2006 report on emergency care entitled *Hospital-Based Emergency Care: At the Breaking Point* highlighted ED congestion caused by diminished access to primary care, a growing rate of uninsured Americans, an aging population, and inadequate hospital and

ED capacity. The IOM suggests that this congestion leads to patient boarding, ambulance diversion, and long waits for ED services. The IOM suggests several ways to address this congestion, including increased utilization of observation and fast-track areas as alternate sites for delivering emergency care, where specialized services can be performed, thus leaving the main corpus of the ED available for patients who are most in need.

We believe that CMS' policy of paying for fast-track services at the clinic rate can substantially diminish hospitals' incentives to build and utilize these areas in the ED. We therefore reiterate the AHA's proposed policy on ED payment with respect to fast track areas:

> **If a hospital with a Type A 24/7 emergency department has a "fast track" area to which some patients are sent for expedited or specialized care, the fast track area is a part of the Type A ED and can bill for the Type A ED CPT codes, regardless of the fast track's hours of operation, as long as the following criteria are met:**
>
> 1. **The fast track is a hospital-based facility which provides unscheduled episodic services to patients who present for immediate medical attention;**
> 2. **The fast track area is physically located within the same building as the 24/7 ED; and,**
> 3. **The 24/7 ED and the fast track share a common registration system.**

HOSPITAL COPS: NECESSARY PROVIDER CAHS

CMS proposes to change CoPs for critical access hospitals that participate under a "necessary provider" grandfather exception. Specifically, in the proposed rule, CMS proposes to disallow necessary provider CAHs to no longer enter into co-location arrangements with hospitals, unless such arrangements are in effect as of January 1, 2008 and the type and scope of services offered by the facility co-located with the necessary provider CAH do not change. CMS also proposes to clarify that off-campus locations involving provider-based facilities or psychiatric or rehabilitation distinct part unit created on or after January 1, 2008 must comply with the distance requirements of a 35 mile drive, or 15 miles on mountainous or secondary roads. Further, CMS proposes that if an off campus location of a CAH violates the distance requirement or the co-location requirement, the entire institution is deemed to be in violation of CAH CoPs, and is therefore subject to termination from the Medicare program.

From the proposed rule, we are unclear to whom the rule would apply. Though the title of the section references necessary provider CAHs, the CoP changes appear to apply to all CAHs, irrespective of their status as a necessary provider. Moreover, the AHA and others have raised questions about which specific provider-based entities within the CAH would be affected by this proposal, since provider-based regulations state that determinations are unnecessary for many types of facilities, including hospices, inpatient rehabilitation units, independent testing and diagnostic facilities, facilities furnishing solely physical, occupational, or speech therapy; ESRD facilities; ambulance providers; and rural health clinics with more than 50 beds.

Further, we are concerned about the effect this proposal would have on all CAHs with respect to the distance requirement. Under this proposal, two CAHs could be 40 miles apart (thus

conforming to the distance requirement for the main hospital), but be unable to provide needed provider-based services at many locations that are midway between the two CAHs because of the distance requirements This is especially concerning because of the unknown effect that the rule would have upon rural health clinics, which are an important source of primary care in California.

Finally, seismic retrofitting, which is required by California state law, is causing considerable disruption in state's hospital industry. To comply with this mandate, some facilities (including CAHs) are considering making temporary – and occasionally permanent - adjustments to their service locations while their original facilities are upgraded to meet the mandate. Though some of these relocations have commenced, others are in the planning stages. CHA is concerned that the proposed changes to CoPs will cause components of affected facilities that are relocating to suddenly violate the distance requirements, thus endangering their CAH status and risk termination.

Because of these concerns, CHA cannot support these proposed changes to CoPs, and urges CMS to withdraw them.

CONTACT

Thank you for the opportunity to comment on the proposed revisions to the OPPS payment policies and on other matters. CHA appreciates CMS'continued efforts to improve the Medicare program, and we are happy to assist the agency however we can.

Please contact me if you have any questions. I can be reached by phone at 202-488-4688, or email jrigg@calhospital.org.

Sincerely,

John Rigg, MHA MPA
Vice President, Federal Regulatory Affairs

JR:

THE AMERICAN SOCIETY OF HEMATOLOGY
1900 M Street, NW, Suite 200, Washington, DC 20036 **ph** 202.776.0544 **fax** 202.776.0545 **e-mail** ASH@hematology.org

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September 11, 2007

Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS 1392-P, Proposed Changes to the Hospital Prospective Payment System and CY 2008 Rates

Dear Mr. Weems:

The American Society of Hematology (ASH) appreciates the opportunity to comment on the proposed changes to the hospital outpatient prospective payment system for 2008. ASH represents approximately 11,000 hematologists in the United States who are committed to the treatment of patients with blood-related disorders. ASH members include hematologists and hematologist/oncologists who provide expert care to Medicare beneficiaries and whose services are frequently covered by the Hospital Outpatient Prospective Payment System (HOPPS). ASH would like to offer specific comments on issues that affect hematologists.

Bone Marrow and Stem Cell Processing Services

ASH is concerned about the APC assignment and the proposed payment level for the bone marrow and stem cell processing procedures, Codes 38207-38215. These services involve the expert processing of bone marrow and stem cells prior to transplantation and include such critical procedures as the therapeutic removal from the graft of certain undesirable cells. Since the inception of the HOPPS program, and until the present time, CMS has failed to recognize and appropriately fund these important CPT codes.

CMS established three "G" codes with which to report these services. Two of the codes were erroneously classified as clinical diagnostic laboratory tests and excluded from HOPPS: G0265 (cryopreservation, freezing and storage of cells for therapeutic use) and G0266 (thawing and expansion of frozen cells for therapeutic use). The third code, G0267 [bone marrow or peripheral stem cell harvest, modification or treatment to eliminate cell type(s) (e.g., T-cells, metatastic carcinoma)], was covered under HOPPS.

ASH appreciates the fact that, after several years of discussion, codes 38207-38215 will now be recognized under HOPPS according to the proposed rule, but we are concerned about their proposed APC assignment. Codes 38207-38209 were assigned to APC 0344, Level IV Pathology, with a proposed payment rate of $54.69. This APC consists primarily of anatomic pathology services, including Codes 88307 and 88309, that involve the handling and preparation of tissue specimens for microscopic evaluation. Clearly, the effort, processes and, therefore, the costs involved in cryopreserving,

thawing and washing bone marrow/stem cells for a potentially life-saving transplant are very different from the costs involved in preparing tissue for diagnostic studies.

ASH, working with AABB, ASBMT and other interested societies, conducted a survey of hospital centers that perform bone marrow transplantation services including some where these highly specialized processing services are performed. We requested data from the centers on direct costs: clinical labor, supplies and reagents. Based on the data we received from seven institutions, the mean and median direct costs of performing these services are as follows:

Code 38207, Cryopreservation and storage – mean $809 and median $500
Code 38208, Thawing without washing – mean $206 and median $144
Code 38209, Thawing with washing – mean $325 and median $206

Assuming direct costs are about 50 percent of total costs; this would indicate that total costs approximate twice the direct cost estimates. This would raise the estimate of total costs to:

Code 38207, Cryopreservation and storage – mean $1,618 and median $1,000
Code 38208, Thawing without washing – mean $412 and median $288
Code 38209, Thawing with washing – mean $650 and median $412

ASH recognizes that eventual reporting under this series of codes will ultimately provide CMS with charge and cost data for these codes. However, at a minimum, these data will not be available until the payment rates are established for CY 2010 based on CY 2008 claims. In the interim, ASH urges CMS to place these codes in an APC that pays substantially more than the $54 amount which will cover only a small fraction of the real costs. ASH suggests that APC 0111, Blood Product Exchange (paying $776) would be an appropriate initial payment level. It would pay substantially less than the costs of freezing and storing the product and somewhat more than the cost of thawing the same material. On average, this APC would be a reasonable interim APC until better data are available in two years.

G0267, currently paid for under HOPPS, is assigned to APC 0110. This is the blood transfusion APC which has a payment rate of $222.44. The data in this APC is dominated by transfusion procedures particularly Code 36430. The median cost data for G0267 indicate only 194 single claims were billed (438 total claims) with a median cost of $405.84. ASH is confident that most of the billings within G0267 are for the lower cost services such as red blood cell removal (Code 38212). On the other hand, codes 38210 (T-cell depletion) and 38211 (tumor cell depletion) are extremely costly services that are performed by only a limited number of facilities and very rarely in the Medicare age group. We have data for five facilities that indicate that the reagent kits alone for codes 38210 and 38211 cost from $5,913 to $7,968 per patient and clinical staff costs range from $270 to $1,344. Thus, the $222 payment rate would cover only a miniscule portion of the costs. ASH, therefore, would like two options for pricing Codes 38210 and 38211:

Option 1—Place Code 38210 and Code 38211 into a higher paying APC. ASH suggests APC 0112, Apheresis and Stem Cell Procedures, with a payment rate of $2.035.93. We think this would be a reasonable interim rate until adequate cost data is collected.

Option 2—Reimburse Code 38210 and Code 38211 on a cost-based method based on a hospital's charges reduced to cost using the cost to charge (CCR) methodology. This would be analogous to the method used for pricing pass-through devices and would also be an appropriate interim measure until data is available for these processing services.

Regarding the other cell depletion codes, 38212-38215, the Society notes that survey data for seven hospitals indicated the following direct costs (clinical labor and supplies) for these codes:

Code 38212, Red Blood Cell Removal—Mean $591 and Median $239
Code 38213, Platelet Depletion—Mean $272 and Median $272
Code 38214, Plasma (Volume) Depletion—Mean $269 and Median $124
Code 38215, Cell Concentration in Plasma—Mean $265 and Median $265

Assuming direct costs are approximately half of total costs, this would result in the following estimates of total costs:

Code 38212, Red Blood Cell Removal—Mean $1,082 and Median $478
Code 38213, Platelet Depletion—Mean $544 and Median $544
Code 38214, Plasma (Volume) Depletion—Mean $538 and Median $248
Code 38215, Cell Concentration in Plasma—Mean $530 and Median $530

In lieu of APC 110, we would recommend that Codes 38212-38215 be placed in a separate APC using the actual median cost data for G0267. This would raise the payment level to the $400 level from the proposed $220 rate of APC 0110. This change is clearly supported by the survey data. When CMS has adequate claims data for the individual codes it might be appropriate to adjust the APC grouping further. However, it is an appropriate and reasonable interim step.

Payment for Radioimmunotherapy Agents

ASH is extremely concerned about the proposed payment rate for Bexxar (I131 Tositumomab), which is a radioimmunotherapy (RIT) agent. Similar issues apply to Zevalin (Ibritumomab Tiuxetan), which is also a RIT. The principle use of a RIT is for the treatment of non-Hodgkin's Lymphoma for patients who have not responded well to a prior course of chemotherapy treatment. There are two major problems with the proposed payment for I131-Tositumomab. First, the initial treatment is considered as a diagnostic procedure. Under the proposed rule, the cost of radiopharmaceuticals for diagnostic as opposed to therapeutic purposes will be "packaged" and not separately paid. Second, the proposed payment level for I131-Tositumomab grossly underestimates the cost of this product.

The complete I131-Tositumomab treatment regimen is provided over 7 to14 days. After an initial treatment, the patient is evaluated through whole body dosimetry to determine if the biodistribution of the agent is acceptable. If it is not, no further I131-Tositumomab treatment is provided. In the proposed rule, CMS indicates its intention to discontinue separate payment for diagnostic radiopharmaceuticals and to package the cost of the agent in the cost of the nuclear medicine procedure. CMS classified the initial dose of I131 Tositumomab as a "diagnostic" so that it would be classified as packaged and given "N" status under HOPPS. This decision is erroneous. All the doses of I131-Tositumomab are intended to be therapeutic and part of a multi-day treatment regimen and thus paid separately. This is the case even if the decision is made not to furnish any further doses because the biodistribution of the initial dose of the agent was not considered acceptable.

It is also our understanding that the proposed payment rate for the therapeutic use of I131-Tositumomab would cover less than half of the $30,000 cost to hospitals. It is clear that the CMS' estimate of costs grossly undervalues actual costs of I131-Tositumomab. Whether this is because of a defect in the cost to charge method (CCR) due to the unwillingness of hospitals to adequately mark up the charges for very costly services (i.e., the phenomenon of charge compression) or for other reasons, unless corrected, this could prove devastating to this important therapy. It may severely limit patient access to this invaluable treatment since hospitals will not be able to absorb a loss exceeding $16,000 per patient. If this occurs it will eliminate one of the few treatment options and perhaps the only treatment option for some patients with non-Hodgkin's Lymphoma who have failed chemotherapy treatment. And, finally, it could have a chilling effect on the development of future drugs and radiopharmaceuticals for treating other forms of cancer and other diseases.

For purposes of the proposed packaging rule, ASH strongly urges CMS to reconsider the classification of I131-Tositumomab as a diagnostic radiopharmaceutical and to treat all doses of I131 Tositumomab as therapeutic. With respect to the level of payment, ASH is not presenting specific recommendations as to how CMS can best fix this problem. The Society understands that this issue was presented at the meeting of the APC Advisory Committee on September 6, 2007 and that several options were proposed. This included paying for the agent as a drug and not as a radiopharmaceutical so that it would be paid at the rate of 106 percent of average sales price (ASP). ASH further understands that the manufacturer has indicated a willingness to submit quarterly ASP prices. Also, the APC Advisory Committee and the manufacturer urged CMS to consider establishing a "composite" APC reflecting the full costs for the entire course of therapy including all the procedural services, radiopharmaceuticals, drugs and supplies. All of these methods would seem promising. However, what is critical is that CMS find ways to substantially improve the payment so that patients are not deprived access to this valuable cancer treatment.

Thank you again for the opportunity to offer these comments. If ASH can provide any further assistance including furnishing the actual survey instrument and survey data, please contact Carol Schwartz, ASH Senior Manager of Policy and Practice, at 202-292-0258 or at *cschwartz@hematology.org*.

Sincerely,

Andrew Schafer

Andrew I. Schafer
President

THERAGENICS CORPORATION®

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September 14, 2007

Via Hand Delivery

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
200 Independence Avenue, S.W.
Hubert H. Humphrey Building
Room 445-G
Washington, D.C. 20201

Ref: CMS-1392-P
Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Proposed Rule

Re: OPPS: Brachytherapy

Dear Mr. Weems:

On behalf of Theragenics Corporation®, I present these comments regarding Medicare's policies for cancer treatment provided through brachytherapy devices under the hospital outpatient prospective payment system (OPPS). These comments respond to the recent proposed rule published by the Centers for Medicare & Medicaid Services (CMS) at 72 *Federal Register* 42628 on August 2, 2007.

Specifically, these comments respond to the section of the proposed rule involving "OPPS: Brachytherapy."

Theragenics Corporation® is based in Buford, Georgia with additional facilities in Garland, Texas and Portland, Oregon. In 1986, Theragenics Corporation® received FDA clearance for TheraSeed®, a radioactive medical device made with palladium-103 that is used to treat solid, localized cancerous tumors. Theragenics® is the only U.S. supplier of palladium-103 material. Theragenics also manufactures and markets an iodine-125 brachytherapy seed.

Theragenics® has been an active participant in discussions with CMS, Congress, and other policymakers regarding the reimbursement and coding of brachytherapy devices and procedures in the outpatient setting. We supported Congress' recent decision to

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NYSE.

Corporate Offices

5203 BRISTOL INDUSTRIAL WAY, BUFORD, GA 30518

phone 770.271.0233 fax 678.482.4909

mandate the creation of separate OPPS payment groups for stranded and non-stranded brachytherapy devices, and we commend CMS for the new codes the Agency recently

established to address this issue. These new codes provide an opportunity for CMS to help protect beneficiary access to these life-saving devices.

However, we have serious concerns with respect to CMS' proposal to pay for brachytherapy devices on a prospective payment basis beginning in calendar year (CY) 2008. As discussed in greater detail below, we urge CMS to take the following actions:

CMS should continue the current payment methodology for brachytherapy devices in the hospital outpatient setting (the "charges adjusted to cost" methodology) for all brachytherapy devices in 2008 and 2009.

A. CMS' top priority should be to ensure ongoing beneficiary access to brachytherapy because of the extraordinary clinical outcomes for cancer patients and the concomitant economic savings achieved by the Medicare program.

B. CMS should continue the current reimbursement methodology for brachytherapy devices while gathering accurate claims data, rather than basing prospective payment rates on unsubstantiated cost assumptions.

C. CMS has the legal authority to maintain the current payment methodology and is not required to implement a prospective payment methodology for brachytherapy devices in 2008 and 2009.

* * * * *

Discussion:

CMS should continue the current payment methodology for brachytherapy devices in the hospital outpatient setting (the "charges adjusted to cost" methodology) for all brachytherapy devices in 2008 and 2009.

In many instances, brachytherapy devices provide the safest and most effective treatment for prostate cancer and other forms of cancer. Therefore, it is absolutely essential that CMS protect Medicare beneficiary access to these life-saving cancer therapies. The cornerstone for ensuring beneficiary access to brachytherapy devices is fair, stable and adequate reimbursement.

Brachytherapy devices are currently paid on a charges adjusted to cost basis. This methodology, which has been in place over the last three and a half years (and for over five and a half years since the implementation of the OPPS), has worked well for beneficiaries, hospitals and the Medicare program. Beneficiary access to brachytherapy devices has been protected and aggregate payments for brachytherapy have remained stable.

Prospective reimbursement rates that do not accurately reflect the costs of brachytherapy devices may create significant barriers to access for individual cancer patients and may place financial pressures on hospitals to take shortcuts in the use of the devices. CMS should proceed cautiously in setting prospective payment rates and ensure that the payments are based on accurate data and do not under- or over-reimburse Medicare providers.

A. CMS' top priority should be to ensure ongoing beneficiary access to brachytherapy because of the extraordinary clinical outcomes for cancer patients and the concomitant economic savings achieved by the Medicare program.

We urge CMS to prioritize ensuring that Medicare beneficiaries continue to have meaningful access to brachytherapy, a well-established modality used primarily in the treatment of cancer. Brachytherapy involves the implantation of radioactive brachytherapy devices in and around cancerous tumors. Although prostate cancer is the most common indication for brachytherapy, brachytherapy also is used to treat breast, liver, eye, brain, esophageal, lung, cervical, skin and many other types of cancer.

Brachytherapy for prostate cancer involves a one-time, minimally-invasive procedure lasting approximately 45 minutes that typically is performed on an outpatient basis. In the case of prostate cancer, the long-term data (15+ years) demonstrate that brachytherapy devices cure cancer at rates that equal or often exceed other clinical options. In fact, the clinical literature now demonstrates remarkable cure rates exceeding 98 percent for prostate cancer using palladium-103 brachytherapy devices.[1]

In addition to the successful treatment of prostate cancer, brachytherapy has lower incidence rates of serious side-effects — including impotence and urinary incontinence — than surgical removal of the prostate (called "radical prostatectomy").[2] The

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[1] Merrick GS, Wallner KE, Butler Wm, Galbreath RW, Allen ZA, Adamovich E, True L. *Brachytherapy in men aged < or = 54 years with clinically localized prostate cancer*, BJU Int. 2006 Aug; 98 (2): 324-8.

[2] Fowler FJ Jr., McNaughton Collies M, Albertson PC, Zietman A, Elliott DB, Barry MJ. *Comparison of recommendations by urologists and radiation oncologists for treatment of clinically localized prostate cancer*. JAMA 2000; 283:3217.

combination of high cure rates and few side-effects makes brachytherapy both a desirable option for patients and a very cost effective treatment for the Medicare program.

In light of these clinical and economic factors, CMS should be especially cautious in changing the reimbursement methodology for brachytherapy devices. As Congress has highlighted in the past, brachytherapy devices are unique in many ways that complicate the application of a prospective payment methodology. Given the current deficiencies with CMS' data, CMS should not proceed with significant changes in this area without understanding the clinical impacts of such changes.

B. CMS should continue the current reimbursement methodology for brachytherapy devices while gathering accurate claims data rather than basing prospective payment rates on unsubstantiated cost assumptions.

CMS does not have accurate data upon which to base prospective payment rates for brachytherapy devices in CY 2008. Late last year, Congress directed CMS to establish new codes for stranded brachytherapy devices used in the hospital outpatient setting. In doing so, Congress intended to ensure that Medicare beneficiaries would continue to have meaningful access to these cancer therapies through separate coding and reimbursement that is fair and adequate. Stranded brachytherapy devices provide clinical advantages over traditional configurations in the treatment of prostate cancer.

Consistent with the legislative mandate, CMS established new codes to distinguish stranded and non-stranded brachytherapy devices, and these codes became effective on July 1, 2007. Since these codes are new, CMS does not have code-specific data to use in establishing prospective payment rates.

In the proposed rule, CMS set the payment rates for stranded and non-stranded configurations for 2008 by making assumptions about how to apply its 2006 data to the new codes[3] (the 2006 data pre-dates the new codes and does not distinguish between stranded and non-stranded devices).

Importantly, there is no meaningful data to support CMS' assumptions. CMS fails to provide a rationale for these assumptions, other than the assumptions "appear to provide a reasonable cost differential" between stranded and non-stranded sources.[4] The fact that CMS describes its methodology using technical language — including references to the use of various percentiles — does not change the fact that these numbers are based in large part on guesswork by the Agency.

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[3] 72 Fed. Reg. at 42748.
[4] *Id.*

CMS should not rush to establish prospective payment rates for stranded and non-stranded configurations, especially when appropriate codes are in place to collect data for future use. By making assumptions and guessing at the payment levels now, CMS risks under-reimbursing or over-reimbursing hospitals for various brachytherapy devices in 2008 and 2009, which could undermine beneficiary access to important cancer therapies.

CMS also erred in making the same assumptions for different categories of devices (isotopes). Specifically, there is no reason to believe that the same assumptions apply across-the-board to iodine-125, palladium-103 and cesium-131 brachytherapy devices.

Although we have concerns regarding CMS' assumptions, we urge CMS to refrain from compounding the problem by modifying the proposed payment levels for these devices on the basis of anecdotal comments that the Agency may or may not receive on the issue of prospective payments levels for the new stranded and non-stranded source codes. Only a comprehensive database that is comprised of accurate data can address the issue of relative payment rates for stranded and non-stranded brachytherapy devices. At this time, no such comprehensive data exists in either the public or private sectors.

Instead of rushing to establish 2008 payment rates that are heavily influenced by assumptions and guesswork on the part of the Agency, we urge CMS to follow a more prudent course of action in which additional data is collected for these new codes.

The current "charges adjusted to cost" methodology that is used in the hospital outpatient setting has worked well for brachytherapy devices over the last three and a half years under Medicare (and for over five and a half years since implementation of the OPPS). We therefore urge CMS to continue the status quo for at least another two years while necessary data is collected.

The problems with CMS' data are not limited to the low dose rate (LDR) brachytherapy devices that commonly are used to treat prostate cancer. There are also significant problems in using CMS' current data to establish prospective rates for high dose rate (HDR) brachytherapy devices.

HDR brachytherapy devices are "renewable" because the devices decay over a 90-day period. These sources can be used to treat multiple patients during this 90-day period. As a result, the true cost of the device depends on the number of patients treated by a hospital within this time period, as well as the number and intensity of the treatments required. These unique characteristics make it difficult to establish fair and adequate fixed reimbursement levels for all hospitals on a prospective basis. Setting prospective payment levels would likely establish perverse incentives that interfere with patient

access in both urban and rural areas throughout the United States, potentially limiting beneficiary access to HDR brachytherapy treatments.

C. CMS has the legal authority to maintain the current payment methodology and is not required to implement a prospective payment methodology for brachytherapy devices in 2008 and 2009.

CMS is not required to establish prospective payment rates for brachytherapy devices in CY 2008 or 2009. Since implementation of the OPPS, CMS has gradually paid for a greater number of outpatient services on a prospective payment basis, although certain services (including brachytherapy devices) have been paid on a charges adjusted to cost basis under the OPPS.

Through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003[5] (MMA) and the Tax Relief Health Care Act of 2006[6] (TRHCA), Congress directed CMS to pay for brachytherapy devices on a charges adjusted to cost basis through the end of CY 2007. CMS is not, however, required to immediately implement a prospective payment methodology for brachytherapy devices in CY 2008 or 2009.

CMS' preference for prospective reimbursement should not obscure the fact that insufficient data exists to ensure that fair and adequate prospective reimbursement rates can be established. Especially in the absence of any problems with the current methodology, CMS should continue basing reimbursement for brachytherapy devices on charges adjusted to costs in 2008 and 2009.

* * * * *

CMS should continue the current charges adjusted to cost payment methodology for brachytherapy devices in the hospital outpatient setting for all brachytherapy devices in 2008 and 2009. There is no immediate need or legal requirement for CMS to change the reimbursement methodology from the status quo.

We urge CMS to implement well-supported and equitable reimbursement policies for brachytherapy devices as a means of ensuring ongoing access for cancer patients and

[5] Pub. L. 108-173, §621(b).
[6] Pub. L. 109-432, Division B, §107(a).

adequate payments for brachytherapy providers. Please do not hesitate to contact Janet Zeman at (770) 831-5123 or ZemanJ@Theragenics.com if we can provide any further information or answer any questions you may have.

Respectfully submitted,

M. Christine Jacobs
President and Chief Executive Officer
Theragenics Corporation®

cc: Janet Zeman, Theragenics

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CEDARS-SINAI MEDICAL CENTER®

September 13, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850.

To Whom It May Concern:

On behalf of Cedars-Sinai Medical Center, a 950 bed hospital located in Los Angeles, California, I am responding to the request for comments on a new proposal to capture pharmacy handling/overhead cost associated with separately payable drugs, published in the Federal Register on August 2, 2007.

CMS proposes to require hospitals to break out the pharmacy overhead cost part of the charge from the drug line item charge and bill it separately using an "uncoded" revenue code. Our principal concerns about the proposed regulations are twofold.

At the time that charges are submitted, the information system does not provide the name of the payer. Based on the proposed requirement, pharmacy staff would have to look up each patient prior to submitting charges to determine the payer status and whether the patient was an inpatient or outpatient.. This would require a significant increase in staffing in order to ensure charges are billed in a timely and accurate manner. Furthermore, the current information system would not be able to bill the same drug two different ways, i.e., 2 charges for Medicare patients and a single charge which includes overhead and handling to other payers

We currently post an average of 8000 charges each day for an average daily census of 850 patients and have a staff of 7.8 FTEs. We estimate that we will have to double the number of staff in order to meet the new workload requirements.

In addition to the increased workload for the billing staff, there is also additional workload for staff responsible for the maintenance of the hospital Chargemaster. Currently there are 30,000 + charge codes for medications in our hospital Chargemaster. The proposed rule will necessitate adding one more code for the drug charge and another code for the handling/overhead resulting in addition to the current code which will still be used to bill other payers. As a result, the

number of codes in the Chargemaster will increase 3 fold (a total of 90,000 + codes) and there will be three charge codes for each medication which increases the potential for billing inaccuracies. Further, this makes the task of maintaining the Chargemaster extremely challenging.

Based on the extreme hardship we would incur as described above, we sincerely hope that CMS will take our comments into consideration and not to implement the proposed changes as Final Rule effective January 1, 2008.

Sincerely,

Thomas M. Priselac

Thomas M. Priselac
President and CEO

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PROVIDENCE
Health & Services

September 14, 2007

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

REF: CMS-1392-P

RE: Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Medicare and Medicaid Programs: Proposed Changes to Hospital Conditions of Participation; Proposed Changes Affecting Necessary Provider Designations of Critical Access Hospitals

Dear Mr. Weems:

On behalf of Providence Health & Services (Providence), I want to thank you for the opportunity to provide our comments on the changes proposed by the Centers for Medicare and Medicaid Services (CMS) to the Hospital Outpatient Prospective Payment System (OPPS). CMS published these changes on August 2, 2007 in the *Federal Register* (Vol. 72, No. 148) and seeks public comment on the revisions.

Providence is a not-for-profit organization extending across five states, including Alaska, Washington, Montana, Oregon and California. The System operates 26 acute care medical centers and hospitals, more than 35 non-acute facilities, physician clinics, a health plan, a liberal arts university, a high school and numerous other health, housing and educational services. In total, more than 45,000 people are employed by Providence. In Alaska, Washington, Montana and Oregon, Providence is sponsored by the Sisters of Providence religious community. In Southern California, the health ministry is co-sponsored by the Sisters of Providence and the Little Company of Mary.

As a Catholic health care system striving to meet the health needs of people as they journey through life, Providence is pleased to submit comments on several areas related to the proposed changes to the hospital OPPS.

APC Relative Weights

For 2007, CMS proposes to use the same methodology it has for a number of years to determine the relative APC weights, including the creation of "pseudo" single claims from multiple procedure claims. The median cost of each APC is compared to APC 0606, the same as in 2006.

Despite CMS' continued efforts to improve its claims data processes, the APC weights remain highly volatile. Over 94 APC weights are lower this year, some by as much as 35% or more. On the other hand, weights increase for 295 APCs, many substantially, and 32 APCs gain more than 35%. None of these changes reflect actual changes in hospital costs for the procedures reported, although comparisons between the proposed rule and APC weights from 2007 are difficult given the increased packaging of services.

The volatility in the APC weights creates tremendous uncertainty for hospitals in planning services and budgeting – processes that are well under way, or complete, for 2007 in many cases. Hospitals that "guess wrong" in these processes may find themselves dramatically affected by a substantial change in the APC weights and may discover it is nearly impossible to maintain a service. Thus, the continued volatility jeopardizes the availability of services to Medicare beneficiaries.

> **Recommendation: Providence again urges CMS to develop a complete, long-term solution to this problem by re-examining the billing system, and convening a panel to consider additional submittal requirements that could substantially improve the data from which the weights are determined. For the near term, we encourage CMS to implement measures to mitigate the effects of the changes in APC weights under the current system, such as limiting the extent of change in any one year.**

OPPS: Packaged Services

CMS plans to initiate specific payment approaches that encourage efficiency in the hospital outpatient setting that it believes will control future growth in the volume of outpatient PPS services. For 2008, CMS proposes to expand the packaging of minor, ancillary services associated with significant procedures into a single payment for the procedure as well as to bundle payments for multiple significant procedures related to an outpatient encounter into a single unit of payment. This means that many services for which hospitals currently receive separate payment will no longer receive separate payment in 2008, according to CMS' proposal.

Providence is concerned that in the drive to significantly increase the number of services that are packaged or formed to create a composite APC intended to moderate the growth in volume and OPPS spending, CMS may be devaluing medical necessity. We appreciate that it can be a fine line between medically necessary services and those that are questionable but we urge CMS to err on the side of caution. In particular, Providence is concerned that the new packaging efforts will create disincentives to provide certain services rather than balance the incentives.

A. Proposed Packaging Approach

Conceptually, Providence supports increased packaging of appropriate services. However, we are concerned about the proposed packaging of the following: all intra-operative services, imaging supervision and interpretation, and observational services.

Intra-Operative Services. Currently, Medicare provides separate payment for HCPCS codes 92978 and 92979 - intravascular ultrasound, heart add-on, as well as codes 37250 and 37251 – intravascular ultrasound, first vessel and each additional vessel add-on (collectively known as IVUS). Experts in the field worked closely with the ICD-9 CM committee to create procedure codes that correspond to these CPT codes in October 2004. Studies have shown that IVUS-guided expandable stent implantation provides a better outcome to patients by decreasing the advent of late stent thrombosis. However, because this process is only a recommended, rather than required, part of the stenting protocol, many hospitals under the packaging proposal by CMS will now have a financial incentive to forgo this procedure, even when the benefits to Medicare beneficiaries are significant.

Recommendation: Providence urges CMS to remove HCPCS 92978, 92979, 37250 and 37251 from the list of packaged intra-operative services and continue to provide separate payment for these beneficial procedures under the OPPS.

Additionally, HCPCS code 75898 (follow-up angiography) will have a status indicator of "N" under the proposal by CMS. This is often the only service performed when a patient has lengthy thrombolytic therapy; the patient may return over several hours or days to see the progression of the therapy.

Recommendation: We urge CMS to modify the status indicator of HCPCS 92978 to "Q" so this procedure may be billed and paid as a separate and only procedure when appropriate.

Packaging of Imaging Supervision and Interpretation Services. The radiology supervision and interpretation (S&I) services would be appropriate to package as the support or dependent service if the surgical services were separately paid. However, most of the surgical codes are packages as well. In these cases, there would apparently be no recognition of or payment for the S&I services.

Recommendation: Providence urges CMS to reconsider the packaging of radiology S&I services when the surgical codes are packaged as well.

Packaging of All Observational Services. Providence does not support the packaging of observational services reported under HCPCS code G0378 (Hospital observation services, per hour). Currently separate payment for such observation service is made for only three conditions – chest pain, asthma, or congestive heart failure. The costs and resource utilization for such patients are obviously much higher than those for patients requiring a lower level of emergency department visit

service. Patients with any of these conditions have a higher acuity and a longer length of stay involving observational services.

Hospitals that specialize in the care of patients with cardiac problems and/or asthma could find themselves severely disadvantaged under the proposed packaging because the costs they incur in providing observation services for patients with these conditions would not be adequately covered under the proposed packaging methodology. This is clearly apparent from the example cited on page 42676 of the Federal Register, (Volume 72, Number 148). Currently a hospital outpatient department providing a separately payable observational service in conjunction with HCPCS code 99285 – Emergency Dept Visit (independent service) would be paid a total of $768.07. Under the proposed packaging policy for observational service the same services would be paid a total of $348.81 in CY 2008. This is a loss of about 55 percent.

We are also concerned about this proposal because it could hurt rural hospitals that frequently use observation care to determine whether patients need to be transferred to other facilities for inpatient admissions.

Recommendation: While we understand CMS' concern about inappropriate incentives of the current OPPS, the proposed packaging of all observational services would not create a neutral incentive in regards to the provision of observation services, but rather a disincentive. **Therefore, Providence urges CMS to reconsider the decision to package all observational services as outlined in the proposed rule.**

B. Proposed Composite APCs

Conceptually, Providence supports the development of composite APCs. Further, we encourage CMS to consider composite APCs for other service combinations. Providence also commends the agency's efforts to determine payments based on multiple procedure claims. We support the proposed composite APCs for Low Dose Rate Prostate Brachytherapy and Cardiac Electrophysiologic Evaluation and Ablation.

However, we are concerned about the ability of composite APCs that stretch across more than one day to accurately reflect the true cost and resource utilization of the related multi-day services. **Thus, until further research and analysis has been completed, Providence is opposed to multi-day composite APCs.**

OPPS: Inpatient Procedures

The inpatient 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 OPPS. There are numerous problems created by the inpatient list 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. In reality, it is the physician, not the hospital, who determines

whether a procedure will be performed in the outpatient or inpatient setting; under current regulations, however, it is only the hospital that may suffer lack of payment based on that decision.

In the past, CMS has responded to such comments by stating "[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." From our perspective, it is of little use for hospitals or their representative organizations to try to educate physicians as to this situation. When it comes to economic issues, physicians, quite understandably, pay little attention to how hospitals are paid.

Recommendation: <u>While Providence supports the removal of the 13 proposed HCPCS codes from the inpatient list, we continue to urge the elimination altogether of the inpatient list because the list is not binding on physicians.</u>

Necessary Provider Critical Access Hospitals (CAHs)

CMS is proposing that if a necessary provider CAH operates a provider-based facility, a psychiatric unit or rehabilitation distinct part unit that is created or acquired on or after January 1, 2008, it must comply with the distance requirement of a 35-mile drive to the nearest hospital or CAH (or 15 miles in the case of mountainous terrain or in areas with only secondary roads).

In the event that a CAH with a necessary provider designation acquires or creates an off-campus facility after January 1, 2008 that does not satisfy the CAH distance requirements, CMS is proposing to terminate that CAH's provider agreement.

Providence strongly objects to the proposal that provider-based locations created or acquired after January 1, 2008 must be more than 35 miles (or 15 miles in the case of mountainous terrain or secondary roads) from any other hospital or CAH. We further object to the loss of CAH status if any new CAH location that meets the provider-based requirements fails to meet this distance requirement.

Approximately 850 of the 1300 CAHs nationally are necessary provider CAHs and are therefore within 35 miles of another hospital or CAH. If this proposal is finalized, these CAHs will be significantly limited, if not in many cases prohibited, from opening new off campus provider-based sites, or converting existing sites to provider-based after January 1, 2008. This is because in many areas, the necessary provider CAHs are located within 35 miles of several other hospitals or CAHs.

The proposal, if adopted, will likely have a disproportionate impact on rural Medicare beneficiaries. Such beneficiaries generally depend on CAHs for their health care needs. CAHs are unlikely to develop new clinical care service sites in outlying rural communities if doing so would threaten their CAH status.

It is worthwhile to note that many state necessary provider plans, which were approved by CMS, used criteria such as population, income and age demographics for geographic areas to determine if a hospital could qualify as a necessary provider.

Recommendation: Providence urges CMS to continue to allow necessary provider CAHs to open or acquire new off-campus provider-based sites after January 1, 2008 irrespective of the distance requirement without losing their CAH status.

IVIG Preadministration-Related Services

Currently, CMS provides separate payment for IVIG preadministration-related services via a new technology APC. In the proposed rule, CMS indicates its intention to continue to provide separate payment for IVIG preadministration-related services, but it will do so through the assignment of HCPCS code G0332 to the new clinical APC 0430 with a median cost of $38.52 for CY 2008 – a reduction of almost 50%. Across Providence, this reduction is estimated to equal $250,000 or more per year.

Over the last several years, hospitals – including Providence – have seen a sharp increase in the number of patients requiring IVIG services as physician offices have reduced or eliminated this procedure from their scope of services. Due to the limited number of legitimate, pedigreed vendors, hospitals often experience difficulty in obtaining product that is safe for administering to Medicare beneficiaries. Additionally, because of its unique nature as well as the allocation process of this product to facilities via group purchasing organizations, hospitals may experience the need to purchase product at extremely high costs in order to fulfill their increased need of the product in some months and experience waste in other months where product cannot be returned to the vendor. All of these factors increase the variability of obtaining this particular product and its costs for all hospitals.

Whether intentional or not, the payment of G0332 at the rate of $75.00 in 2007 served as a buffer for this variability. Although the payment rate was usually greater than the cost of preadministration-related services, this excess served, in part, to compensate hospitals for the extraordinary costs required to secure product in order to meet demand. Without this buffer, many hospitals may reduce or eliminate these procedures from the scope of services they provide, placing additional and financially burdensome responsibilities on those hospitals that continue to provide IVIG services.

Recommendation: While Providence recognizes that CMS should not "subsidize" the price of IVIG through the payment of IVIG preadministration-related services, we urge CMS to reconsider the almost 50% reduction in payment for these services without also revising the payment structure for IVIG. One possible solution would be to pay for IVIG based on vendor-specific costs. Hospitals are "locked in" to a particular vendor because of historical usage and allocation methodologies; a vendor that provides IVIG at a rate close to the reimbursement rate from Medicare in one year may raise their rates to be much higher than CMS payments in the next year. Hospitals are not in a position to bargain or switch vendors based on allocation models, and thus are at the mercy of their particular vendor. Without some type of link between the vendor supplying the IVIG and the payment from CMS, hospitals will continue to experience the current variability of costs and no ability to mitigate this variability through the buffer of the current rate of payment for preadministration-related services for IVIG.

Quality Data

Providence strongly supports the move to require hospitals to report outpatient measures, and we are very pleased that CMS chose not to utilize the surrogate inpatient measures originally suggested.

We agree with many of the selected measures in concept, but note that additional refinement needs to occur to bring the quality measures into the realm of the acute care outpatient setting. Without seeing the "to be developed" specifications, it is difficult to understand exactly which patient population is being measured, with the exception of the ED-AMI measures. For instance, the surgery-related measures might come from several areas in the hospital outpatient setting.

Some of these proposed measures are carried over directly from the PQRI measure sets, and Providence believes there may be some advantages to aligning the PQRI with outpatient quality measures – such as creating incentives for cooperation between physicians and hospitals.

However, we strongly object to the last measure – HbA1c measurement for diabetics – in the outpatient setting. This is an outcome measure that is totally dependent on physician office practice and patient compliance. For the hospital outpatient setting, the only possible thing that is under the hospital control is whether we measure the HbA1c when a diabetic patient is seen, and there is no evidence suggesting that this should always occur. This measure does not assess the outcome of any care that is provided in a hospital outpatient setting (ED, same day surgery, etc.).

Recommendation: <u>Although we support the reporting of quality measures in the hospital outpatient setting, Providence urges CMS to remove the measure related to HbA1c <9 for diabetics from the list of measures to be reported.</u>

OPPS: Device-Dependent APCs

Proposed Payment When Devices Are Replaced with Partial Credit to the Hospital

Providence has concerns with the CMS proposal requiring that hospitals report occurrences of devices being replaced under warranty or otherwise with a partial credit granted to the hospital as well as the proposed payment reductions for such cases. The public identified several concerns when a similar process was proposed in the hospital inpatient prospective payment system (IPPS) for FY 2008, specifically:

- The 20% threshold for device replacement is too low and does not take into account the administrative burden of manually processing the claims
- When returning an explanted device to a manufacturer, hospitals may wait more than eight weeks to receive word that the manufacturer will replace the device and give a partial or full (or zero) credit. This significant time delay would prevent hospitals from submitting claims immediately following a replacement procedure.

Operationally it will be difficult to implement the process proposed by CMS to reduce payment when devices are replaced with a full or partial credit to the hospital.

Recommendation: **Providence urges CMS to adopt a payment process similar to the process recently finalized for the hospital IPPS in regards to devices that are replaced with a full or partial credit to the hospital. Specifically, we urge CMS to implement a threshold of 50% of the device cost before instituting any payment reduction. Additionally, Providence urges CMS to allow providers the choice of either 1) submitting a claim immediately after the replacement procedure without the HCPCS partial credit modifier and submit a claim adjustment with appropriate modifier at a later date once the credit determination is made; or 2) allow hospitals to hold the claim until a determination is made on the level of the credit.** Such changes would align the OPPS proposal for appropriate payment to hospitals receiving a full or partial credit for replaced implantable devices with the process recently finalized in the hospital IPPS rule for FY 2008.

OPPS: Hospital Coding and Payments for Visits

Providence agrees with CMS that, at this time, there is no need for national guidelines for hospital coding of emergency department and clinic visits. The current system in which hospitals create and apply their own internal guidelines to report emergency department and clinic visits is more practical and appropriately flexible for hospitals.

In closing, thank you for the opportunity to review and comment on the proposed changes to the hospital OPPS published in the *Federal Register* on August 2, 2007. Please contact Beth Schultz, System Manager, Regulatory Affairs, at (206) 464-4738 or via e-mail at Elizabeth.Schultz@providence.org if you have questions about any of the material in this letter.

Sincerely,

John Koster MD

John Koster, M.D.
President/Chief Executive Officer
Providence Health & Services

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CEDARS-SINAI MEDICAL CENTER®

September 13, 2007

Mr. Kerry N. Weems, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Subject: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates

Dear Mr. Weems;

On behalf of Cedars-Sinai Health System, a 950 bed hospital located in Los Angeles, California, I am pleased to comment on the Outpatient Prospective Payment System (OPPS) proposed rule for calendar year 2008 (CY2008). In addition to these comments, we support the comments and recommendations of the American Hospital Association (AHA) and the California Hospital Association (CHA).

In its written comments accompanying the proposed rule, CMS emphasizes the need for increased "packaging" of ancillary services, inexpensive drugs, medical supplies, implantable devices, and other ancillary services associated with a procedure into a single payment for the procedure. CMS states that increased use of "packaging" and further use of "bundling" services into a single course-of-care payment promotes provider efficiency while also stabilizing payment volatility through the law of averages.

For CY 2008, CMS proposes to package the following HCPCS codes into payment for the primary diagnostic or therapeutic modality to which it believes they are ancillary and supportive:

- Guidance services;
- Image processing services;
- Intraoperative services;
- Imaging supervision and interpretation services;
- Diagnostic radiopharmaceuticals;
- Contrast media; and,
- Observation services.

Cedars-Sinai Health System has reservations about packaging certain ancillary items and services, particularly where increased packaging may lead to poor adaptation of new technology, or may lead perversely to diminished use of more efficient treatment modalities. For the services that CMS proposes to package for the CY 2008 OPPS, we have particular concern with packaging of observation services for the reasons stated below. Observation units, which are sometimes referred to as clinical decision units (CDUs), are an increasingly important area that exist in our hospital which allow for monitoring "stable" emergency patients over a period of time before making a decision about whether or not to admit a patient to an inpatient unit. Over time, CDUs have proven their efficacy in diminishing hospital overcrowding while assuring continuity of care and, by substituting for inpatient short stays, lowered costs to

the Medicare program. However, in spite of several recommendations on the part of the APC panel and various stakeholder groups, CMS has not expanded the list of diagnoses for which observation services are payable beyond asthma, chest pain, and congestive heart failure. In the CY 2008 OPPS rule, CMS proposes to expand packaging to include observation services into the primary APC to which it is ancillary, which would, CMS believes, effectively expand the number of diagnoses for which observation services would be payable.

We believe that packaging observation services may have the untoward effect of discouraging CDU development. While observation services are separately payable, hospitals have a clear incentive to code to utilize observation when it is clinically indicated and reimbursable under present regulation, because if the observation stay isn't coded for, the hospital cannot receive payment for the service. However, if the hospital receives no additional payment for observation services, and instead these payments are packaged in an APC for an ED stay, incentives to code for observation services will disappear. Because of declining documentation, the costs for observation services may be lost from our hospitals' cost reports, thereby diminishing payment in the long run.

We believe that separate payment for observation services provide a tangible incentive for hospitals to consider making the capital and human resources investments necessary to open CDUs and, as the patient population becomes older and more medically needy, expand existing CDUs.

Were CMS to bundle observation services into a separately payable independent service relating to a disease or condition, the explicit incentive for establishing a CDU would be lost. We believe that this would lead to fewer hospitals considering establishing a CDU, and instead continuing to admit beneficiaries to inpatient beds, thereby doing nothing to mitigate ED overcrowding, and raising costs to the Medicare program.

Due to the analysis of claims data, packaging observation services will redistribute outpatient dollars in such a way that observation beds that are coded appropriately will experience a net loss of revenue from the proposal, while hospitals who don't use observation services, or who don't code appropriately will realize gains. The analysis strongly suggests a perverse incentive, where hospitals who have established CDUs to, as the IOM states "...improve reduce boarding and diversion, avoid expensive hospitalization, and [sic] contribute improved management of common ambulatory-care sensitive conditions" are penalized by a net loss of CDU-related revenue.

While Cedars-Sinai Health System supports CMS' goal of expanding the diagnoses for which observation services are payable, we believe that packaging this service into payment for other separately payable services would suppress hospitals' incentives to create new CDUs, and unfairly penalize those institutions who are currently using and coding appropriately for observation services. We urge CMS to reconsider packaging observation services for CY 2008, and revisit the proposal when observation services become more widely adopted by the hospital community. For the interim, we strongly suggest that CMS continue paying separately for observation, but that it removes condition-specific criteria for payment, as per the IOM recommendation regarding CDUs.

In the proposed rule, CMS proposes developing two "composite" APCs, which would be a single payment for a bundle of separately paid services performed in a single-day encounter or multi-day episode of care. Like "packaged" services above, the agency believes that these composite APCs will give hospitals greater incentives for efficient care.

As previously noted, Cedars-Sinai Health System is generally supportive of increased use of packaging and bundling in the outpatient PPS, however CMS notes in the proposed rule that it requires input from providers about which services would be appropriate candidates for these schemes. We believe that CMS should continue to actively engage with the provider community and the APC Panel in further development of composite APCs, not only to discern which procedures are ancillary or supportive for purposes of packaging, or which major services can be bundled into a single course-of-care payment, but to evaluate whether untoward consequences may occur as the result of bundling and packaging.

In prior rulemaking cycles, CMS expressed concern that it did not have sufficient evidence to support using the median per diem cost produced by the current year's data. In CY 2006, for example, CMS voiced its belief that cost report-based reduction to the per-diem for partial hospitalization programs (PHP) would drop the payment rate to below the cost of providing PHP services, and scaled back a derived 44 percent reduction to 15 percent. Unlike in other areas of the OPPS, where cost report data are derived solely from hospitals, data for community mental health centers (CMHCs) are used in PHP cost analysis. For the past several years, CMS remarks that it has observed considerable volatility in CMHC data. In the CY 2008 proposed rule, the agency remarks, "CMS believes that some CMHCs have manipulated their charges in order to inappropriately receive outlier payments."

For CY 2008, in an effort to better understand PHP costs, CMS drilled down to the PHP unit of service level. Under CMS policy, all PHP programs must provide at least three units of service per day in order to properly bill Medicare for the per diem. However, CMS analysis indicates that 64 percent of CMHC PHP days were days where 3 or fewer services were provided, while 34 percent of days that hospitals were paid were days where 3 or fewer services were provided. CMS claims that per diem rates were predicated on a much higher assumption of service delivery, and so the agency proposes cutting the per diem for all settings from $233.37/day in CY 2007 to $178/day in CY 2008; this would represent a cut of approximately 24 percent to PHP services.

We would also like to illustrate the "ripple effect" cuts to PHP have on other outpatient mental health services. As CMS noted in the preamble to the proposed rule on composite APCs, it is long time CMS payment policy to limit the aggregate payment for specified less intensive mental health services furnished on the same date to the payment for a day of partial hospitalization. Other institutions provide less intensive mental health in the outpatient setting, which is paid on a per-unit basis until it reaches the PHP per diem payment cap. Several of these institutions have stated that they have chosen to provide outpatient mental health services in this manner rather than under the auspices of a PHP program because they find the administrative difficulties involved in running a PHP program to be more troubling than the potential economic gains that are lost through the PHP cap. Importantly, Cedars-Sinai Health System provides three or more units of service per beneficiary per day in treatment in their outpatient mental health (non-PHP) programs, and thus have non-PHP outpatient mental health programs that are very similar to PHP with respect to intensity and setting. A cut to the PHP per diem, especially a cut as large as that which is proposed in the proposed rule, would diminish beneficiary access not only to PHP, but – due to the reduction of the PHP per diem payment cap - also to outpatient mental health services which are paid on a per unit of service basis.

Moreover, based on CMS' own data, that there appear to are substantial differences in PHP costs and service intensity between the hospital and the CMHC setting. With respect to service intensity, CMS analysis indicates hospital-based PHP programs tend to have a greater number of days where more than three units of service were performed, and that hospitals' per diem costs are higher than those of CMHCs, irrespective of the amount of service performed. We

also note that CMS' proposed $178 per diem is amount equal to the agency's estimate of CMHC costs for all days, taking into account the lower volume of services delivered per day. We believe this payment to be completely inappropriate for hospitals, which tend to deliver a more intensive PHP care and who have higher per diem costs. CMS analysis of hospital-based PHP median per diem cost for days with four units of service or more (which occurs in the large majority of hospital-based PHP days) is $218 per day, which we believe is much closer to the cost of care provided in hospital-based PHP programs than the $178 proposed in the rule.

Finally, we wish to underscore that PHP care is intensive outpatient care which allows seniors to remain in their community while receiving needed mental health care, an important aspect of community-based care models. Moreover, PHP is widely regarded as a substitute to inpatient psychiatric hospitalization, which tends to be more expensive for Medicare and more disruptive to beneficiaries. Cuts to PHP, especially cuts of this magnitude have real potential to curtail provision of this much needed, cost effective, community based alternative to hospitalization. The proposed cuts would affect beneficiary access not just to PHP, but to other outpatient mental health programs, and may prompt more inpatient hospitalization, thus increasing costs to the Medicare program. Cedars-Sinai Health System strongly opposes CMS' proposed cuts to PHP, and urges the agency to reconsider its ongoing rate cuts to ensure adequate beneficiary access to PHP services. Further, we suggest that CMS consider providing differential per diem payments based on the setting and intensity of services provided during the PHP day.

For the proposed rule, CMS rejects an APC Panel recommendation that would have implemented a three phase plan to address pharmacy costs in the OPPS. In the first phase, the APC Panel recommended that CMS establish a system of defining pharmacy overhead categories for outpatient drugs that require different levels of outpatient resources, and categorize the drug handling and administration resources required as low, medium, and high. Second, CMS would review outpatient pharmacy overhead estimates from GAO and MedPAC, and consider stakeholder survey data. Third, CMS would establish a mechanism whereby providers could bill pharmacy overhead costs on claims data, but using HCPCS codes that correspond with the aforementioned low/medium/high taxonomy. CMS ultimately rejects this recommendation as being inconsistent with the overall goal of increased bundling and packaging.

Rather, CMS proposes that providers remove the pharmacy overhead charge from the charge for the drug or biological and instead report the pharmacy overhead on an uncoded revenue code line on the claim. To aid in bundling, this policy would apply to all drugs and biologicals, irrespective of whether the drug or biological is packaged or separately payable. The exception to this proposed policy is radiopharmaceuticals, for which overhead and handling are reflected in charges.

CMS intends to use this policy as a transitional step towards greater bundling of part B pharmaceuticals. Once adequate data are collected, CMS indicates that it will package appropriate overhead for the drug or biological with the procedure or procedures to which they are most closely associated.

As stated previously, Cedars-Sinai Health System is strongly in support of increased packaging and larger bundles of single payments in the OPPS. We believe that these payment reforms will lead to enhanced efficiency and less volatile pricing while simultaneously aligning incentives for appropriate care. However, we don't believe that CMS' transitional step of reporting the pharmacy overhead on an uncoded revenue code line on the claim is achievable by CY 2008. We believe that the administrative burden involved in re-pricing all part-B pharmaceuticals and biologicals cannot be reasonably accomplished in so short a time frame. Moreover, we believe

that it would be exceedingly time-consuming to derive an allocation resource use on a per-drug basis.

Cedars-Sinai Health System opposes CMS' proposed rule change at this time. Rather, we suggest that CMS reconsider methods for developing median pharmacy overhead costs in like drugs, perhaps using the APC Panel's proposed taxonomy. CMS could then package median pharmacy overhead payments for administratively similar drugs into appropriate APCs without requiring hospitals to assume the enormous burden of re-pricing and developing drug and facility-specific resource utilization estimates for thousands of drugs in outpatient pharmacies.

In the CY 2007 OPPS proposed rule, CMS promulgated a policy that reduces reimbursement for those APCs where the hospital is replacing a faulty device for a patient for whom the previous device has failed, and when the hospital receives full credit for the cost of the device from the manufacturer. Since 2007 however, the agency has received numerous question from provider groups regarding payment and reporting when the hospital replaces a device, but receives only partial credit to the manufacturer.

CMS now believes that hospitals should report occurrences of devices being replace under warranty or with partial credit granted to the hospital so that they may be able to identify systematic device problems and adjust claims accordingly. To do so, CMS proposes a HCPCS modifier for CY 2008 that would be reported in all cases where the hospital receives partial credit for a replaced device. Further, the agency proposes to reduce the payment of the APC into which the device cost is packaged by one half of the amount of the offset amount that would apply if the device were replaced at no cost (or with full credit) from the manufacturer. However, it would only do this in instances where the device credit is equal to or greater than 20 percent of the cost of the new replacement device

CMS states that it sets the threshold for reporting at 20 percent because if the agency were to take a 50 percent discount for replacement devices where the hospital received less than 20 percent of costs reimbursed by the manufacturer, it would be reimbursement that is "too low" for the cost of the replacement procedure. Further, the administrative burden in reporting discounts of less than 20 percent would outweigh the savings to the program.

Cedars-Sinai Health System appreciates CMS' thoughtful approach to this problem. We agree that the administrative burden associated with reporting and changing reimbursement for devices where less than 20 percent of the cost of the device was credited to the hospital outweigh the savings to the program. However, we are concerned that CMS is adjusting payment for the device portion of the APC by 50 percent in instances where the credit realized by the hospital may be more than twenty but less than 50 creates the problem of inadequate reimbursement for these devices.

With implantable devices in most hospitals, it is the physician who is performing the implantation procedure and not the hospital that chooses the implantable device. Moreover, we believe that it is not hospitals' role to assess the failure rates of implantable devices even in instances where the hospital is empowered to make purchasing decisions regarding these devices. Ultimately, when implantable devices fail it is almost never the fault of the hospital OPD, who rarely make the purchasing decisions and who don't have the technical capacity to assess device failure. Yet the CMS proposal would force hospitals to absorb the difference between the discount offered by the manufacturer and the payment discount from CMS. We believe this is unfair, and we oppose this aspect of the proposed rule. Rather, we suggest that the 20 percent threshold stay in place (for the reasons outlined in the proposed rule and above), but that CMS match the amount of the discount against to the payment adjustment. In this manner, CMS should continue to realize savings to the program from devices replaced with partial credit to the

hospital, but would not penalize hospitals unfairly for device failure that occurs at no fault to the OPD.

In the proposed rule, CMS responds to a 2006 congressional mandate to formulate measures for use in a hospital outpatient quality reporting program. Per congressional instructions, CMS must develop an array of hospital outpatient quality measures, that hospitals must report upon completely and adequately in order to receive a full market basket payment update. If the hospital is unable to comply, they will receive the market basket update minus 2 percent.

To formulate the quality reporting measures, CMS turned to the hospital quality alliance (HQA), and proposes to use ten measures that have received preliminary HQA approval as its OPPS measures for CY 2008. These measures include five relating to patients treated for myocardial infarction (MI, or heart attack) in the ED and then transferred to another facility for definitive care, four additional measures relating to physician care outside the ED, and Hemoglobin A1c levels, which CMS regards as an intermediate outcome measure.

Noticeably absent from the proposed rule, however, are any indications about how the measures would be implemented. We are particularly concerned about PRRI #1: Hemoglobin A1c (HbA1c) levels. While we recognize the important role that HbA1c plays in managing the care of the chronically ill diabetic, we believe that it is unnecessary to assess HbA1c in diabetics in all OPD encounters, and ask that CMS consider limiting reporting requirements under some circumstances. For example, an HbA1c may be unnecessary when a patient requires suture care for a simple laceration in the ED, though it may be more important when the patient is receiving multi-day outpatient therapy. Further, we suggest that this measure and several others in the proposed set for CY 2009 and beyond are measures principally related to ongoing or primary care. While CHA recognizes the validity of these measures for patients receiving ongoing ambulatory or extensive acute care, we question their utility in single encounter outpatient and minor procedural settings.

As CMS implements the OPD pay for quality reporting initiatives, we strongly suggest that the agency proceed cautiously and give careful consideration to a set of criteria that govern what quality measures must be reported upon and in what circumstances, especially with regards to primary care-focused PQRI measures.

As CMS implements the OPPS pay for quality reporting initiative, we note that it will require our hospital to submit notice of participation by November 15th 2007. While this timeframe may allow for adequate time for us to submit our application, we have concerns that we may not have sufficient time to purchase and install new systems to report on the OPD measures, and train OPD staff in time for a January 1 2008 implementation. We are also concerned that CMS' requirement that we submit our IPPS pay for quality reporting applications in August may create the perception that the necessary application has already been submitted and we may inadvertently miss the OPPS application deadline. While we appreciate and support CMS' proposal that hospitals be considered "participating" until they notify the agency otherwise, in the future, we encourage CMS to consider a unified application and deadline, which would help mitigate administrative burden associated with duplicative data entry, and help to mitigate confusion around application timeframes and deadlines.

Cedars-Sinai Health System is very concerned about CMS' proposed outpatient pay for quality reporting initiative as described in the proposed rule. The measures have not been field-tested, and one (HbA1c) appears to have only a tenuous relation to OPD quality for many outpatient procedures and care, especially for non life-threatening OPD ED visits, and minor procedures. Further, CMS' proposed timeframe is extremely short, and we find the application deadlines confusing. For these reasons, we urge CMS not to adopt the OPPS pay for quality reporting

initiative in the final rule. Rather, we suggest that CMS utilize the ensuing year to address many of the details that were not included in the proposed rule, and re-propose outpatient quality reporting for CY 2009.

Cedars-Sinai Health System shares CHA's and AHA's concern about CMS treatment of part A and part B ED visits, especially with respect to its payment policy for "fast track" areas of EDs. In general, fast track areas function as a low-acuity, high volume area of the ED that handles lower acuity complaints, thereby leaving the main corpus of the ED available for the badly ill and injured. Further, we note that the IOM, in its 2006 report on emergency care entitled *Hospital-Based Emergency Care: At the Breaking Point* highlighted ED congestion caused by diminished access to primary care, a growing rate of uninsured Americans, an aging population, and inadequate hospital and ED capacity. The IOM suggests that this congestion leads to patient boarding, ambulance diversion, and long waits for ED services. The IOM suggests several ways to address this congestion, including increased utilization of observation and fast-track areas as alternate sites for delivering emergency care, where specialized services can be performed, thus leaving the main corpus of the ED available for patients who are most in need.

We believe that CMS' policy of paying for fast-track services at the clinic rate can substantially diminish our hospitals' incentives to build and utilize these areas in the ED. We therefore reiterate the AHA's proposed policy on ED payment with respect to fast track areas:

If a hospital with a Type A 24/7 emergency department has a "fast track" area to which some patients are sent for expedited or specialized care, the fast track area is a part of the Type A ED and can bill for the Type A ED CPT codes, regardless of the fast track's hours of operation, as long as the following criteria are met:

1. The fast track is a hospital-based facility which provides unscheduled episodic services to patients who present for immediate medical attention;
2. The fast track area is physically located within the same building as the 24/7 ED; and,
3. The 24/7 ED and the fast track share a common registration system.

Thank you for the opportunity to comment to the Outpatient Prospective Payment System proposed rule for calendar year 2008.

Sincerely,

Thomas M. Priselac

Thomas M. Priselac
President and CEO

(86)

NATIONAL ASSOCIATION OF EPILEPSY CENTERS
NAEC

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[illegible] 14 P 2:05

September 14, 2007

Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Room 445-G
Washington, DC 20201

Re: CMS-1392-P, Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates

Dear Acting Administrator Weems,

The National Association of Epilepsy Centers (NAEC) would like to comment on the section of the Hospital Outpatient PPS proposed rule OPPS: Packaged Services. NAEC is concerned with CMS' proposal to package and assign the status code N to the functional brain mapping CPT code 96020. We do not oppose the packaging of the codes, but ask that the code 96020 be assigned Q status, allowing for separate payment when the service is provided with the functional MRI (fMRI) code 70555. The APC Advisory Committee also made this recommendation at its recent meeting.

NAEC represents approximately 113 comprehensive epilepsy centers in the US that provide specialized diagnostic and treatment services to patients with severe or intractable epilepsy. The Centers utilize an array of diagnostic tests to accurately identify the cause and location of a patient's seizures and to determine if the patient is a candidate for medical or surgical treatment.

If it is determined that the patient is a candidate for epilepsy surgery, functional brain mapping (96020) is often performed for pre-operative mapping of language function and motor function and to determine their anatomic location relative to the seizure focus. The patient's clinical status requires neurofunctional testing administered by a neurologist or neuropsychologist during the fMRI (70555). The neurologist or neuropsychologist is present during fMRI acquisition, presents or supervises the patient's neurological or behavioral activities during acquisition, and participates in interpreting which BOLD signals correspond to which brain functions and what the risks are in removing such areas.

While we recognize CMS' interest in packaging services that are commonly performed in conjunction with other primary services the functional brain mapping code is a distinct service, not performed by the radiologist or technologist providing the fMRI. Functional brain mapping

5775 Wayzata Boulevard, Minneapolis, MN 55416 Phone 952-525-4526 Fax 952-525-1560 www.naec-epilepsy.org

testing is performed on a relatively small number of patients in preparation for epilepsy surgery or another neurosurgical procedure. More commonly, fMRI is performed without functional brain mapping, but in the epilepsy center it is more typical to perform both tests in the same session. Always packaging this service would result in inadequate compensation for the limited number of hospitals with specialized epilepsy centers. We ask that 96020 be assigned Q status to allow for separate APC payments when it is provided with the fMRI.

Thank you for the opportunity to submit these comments. Please contact Ellen Riker, (Ellen@marcassoc.com), NAEC's Washington Representative for additional information.

Sincerely,

Robert J. Gumnit, MD

Robert J. Gumnit, MD

President