September 14, 2007

BY ELECTRONIC DELIVERY

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Room 445–G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates [CMS-1392-P]

Dear Acting Administrator Weems:

The California Healthcare Institute (CHI) appreciates this opportunity to comment on the Calendar Year (CY) 2008 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgery Center (ASC) proposed rule published on August 2, 2007 (the Proposed Rule).1 CHI represents the full biomedical sector of the California economy and unites more than 250 of California’s leading biomedical firms, universities, and private research institutes in support of biomedical science, biotechnology, and pharmaceutical and medical device innovation. California is the global leader in biomedical R&D, with more than one-third of all U.S. biotechnology and medical device firms, turning scientific discoveries into medical products at an unprecedented rate. California companies lead the nation in bringing to market frontline therapies and devices for diseases such as AIDS, breast cancer, heart disease, stroke, and diabetes.

As the advocate for California’s biomedical industry, CHI appreciates CMS’ commitment to refine the OPPS to increase payment accuracy for outpatient procedures and services as well as drugs.2 CHI believes it is particularly important that CMS’ reimbursement policies encourage new scientific breakthroughs that allow procedures to occur faster, more accurately, and with less invasive approaches that minimize risk and recovery times for beneficiaries. This is even more important as OPPS rates will be used to set ASC payments in 2008 and beyond.

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2 Throughout our comments, we use “drugs” to refer to both drugs and biologicals.
Toward this end, CHI continues to be concerned by the agency’s failure to adjust payment rates to account for charge compression. Charge compression leads to the overestimation of the costs of low cost items and the underestimation of the costs of high cost items. It likely is the single most critical factor deterring patient access to innovative drugs and medical devices within the OPPS -- and soon the ASC payment system as well. Inaccurate ambulatory payment classifications (APCs) that do not adequately account for the costs associated with newer drugs and devices slow innovation instead of rewarding it. Accordingly, we urge CMS to develop a methodology to address charge compression as soon as possible and to work with stakeholders throughout the year to ensure that an appropriate adjustment can be implemented for CY 2009.

Moreover, CHI is concerned about CMS’ proposal to “improve efficiency through payment for larger bundles of services”\(^3\) by expanding packaging to seven new categories of items and services. Although we support the agency’s goal of improving efficiency, we are concerned that additional packaging could compromise patient access to advanced medical technologies and high quality care. It is critical that CMS release additional data regarding its proposal and that stakeholders have ample time to analyze it before the agency’s proposal is finalized. In order to ensure that the agency has robust data to set appropriate payment rates in the future, CMS should clearly require hospitals to submit correct and complete coding for any items and services the agency ultimately packages.

In addition to these general comments that are critical for both drug and device technologies, CHI has the following concerns regarding CMS’ proposed payment changes for devices:

- The rate-setting methodology for device-dependent APCs should ensure stable payment rates and require hospitals to use C-codes.
- The New Technology APC and pass-through application processes and the transition of technologies to clinical APCs should be more consistent and transparent.
- CMS should use external data to ensure rates for device-related APCs are appropriate.

With respect to CMS’ proposed payment changes for drugs and radiopharmaceuticals, CHI is deeply concerned that the proposed rate of average sales price (ASP) plus five percent for separately paid drugs without pass-through status is not adequate to reimburse hospitals for their acquisition costs, let alone their pharmacy service costs. CHI believes CMS’ proposal to reduce reimbursement for many separately paid drugs while failing to pay adequately for pharmacy service costs will significantly affect hospitals’ ability to provide these essential therapies to

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\(^3\) CMS Fact Sheet, Payment Policy Proposals for Hospital Outpatient Services in 2008 Emphasize Value-Based Purchasing, July 16, 2007.
Medicare beneficiaries. To ensure that hospitals receive appropriate reimbursements for providing advanced drugs to Medicare beneficiaries, we recommend the following:

- Reimbursement for drugs under the OPPS should be no less than ASP plus six percent;
- CMS should continue to work with stakeholders to develop suitable methods of reimbursing hospitals for pharmacy service and handling costs and not require hospitals to report pharmacy overhead charges on an uncoded revenue code line as proposed;
- CMS should eliminate the bundling threshold and pay separately for all drugs with Healthcare Common Procedure Coding System (HCPCS) codes as it does in the physician office setting, including all radiopharmaceuticals and contrast agents;
- CMS should not apply an equitable adjustment to any drugs;
- CMS should analyze potential edits to correct claims data for radiopharmaceuticals and continue to use the current payment methodology for radiopharmaceuticals in the meantime;
- CMS should continue to pay separately for contrast agents;
- The agency should continue to pay pre-administration-related services for intravenous immune globulin (IVIG) at the 2007 rate and create a new permanent add-on payment to ensure beneficiary access to this critical treatment;
- CMS should be cautious when considering which drugs no longer qualify for pass-through payments; and
- The agency should pay for concurrent infusions, particularly if it continues to package lower cost drugs.

We discuss each of these recommendations in more detail below.

I. PROPOSED UPDATES AFFECTING OPPS PAYMENTS

A. CMS should develop a methodology to address charge compression and work with stakeholders throughout the year to ensure that an appropriate adjustment can be implemented for CY 2009. (APC Relative Weights)

As mentioned above, CHI believes charge compression is likely the single most critical factor deterring patient access to innovative drugs and medical devices within the OPPS. Developing a methodology to correct for this phenomenon is even more critical as APC weights will be used to set ASC rates in 2008 and beyond. CMS’ current rate-setting methodology applies a single cost to charge ratio (CCR) to all drugs and devices, even though hospitals tend to mark up lower cost items and services more than higher cost ones. This methodology leads to inaccurate payments for procedures involving drugs and devices because the costs of low cost
items tend to be overestimated and the costs of high cost items tend to be underestimated.

In recognition of the importance of charge compression, CMS contracted with RTI International (RTI) to study its impact in the inpatient ratesetting methodology.\(^4\) The Proposed Rule acknowledges that this study has “obvious importance for both the OPPS and the IPPS”\(^5\) yet the agency does not propose to implement any of the changes proposed by RTI.\(^6\) Therefore, the reimbursement challenges resulting from charge compression persist, creating inaccurate payments for many APCs related to higher cost drugs and devices.

CHI urges CMS to develop a methodology to address charge compression as soon as possible. Rather than wait until the CY 2009 proposed rule to share the proposed methodology with stakeholders, we urge the agency to work with stakeholders throughout the year to ensure that an appropriate adjustment can be implemented for CY 2009. Although we recognize that the subject of charge compression is outside the scope of the Advisory Panel on APC Groups’ (APC Panel) charter, we ask CMS to call a town hall or other public meeting in the winter of 2007 or early spring of 2008 to obtain stakeholder input on this critical issue.

B. CMS should study the potential effects of expanding packaging and consult with stakeholders before finalizing its proposal to expand packaging to seven new categories. (OPPS: Packaged Services)

In the Proposed Rule, CMS proposes to “package payments into larger payment bundles to promote the stability of payment for services over time” and to “establish incentives for efficiency through larger units of payment.”\(^7\) CHI supports these overall goals; however, without further detail as to the agency’s exact process for bundling its proposed items and services, we are concerned that these proposals will bundle items and services in such a manner that payment rates may not be adequate and beneficiary access to appropriate care will be compromised as a result. Specifically, CMS proposes to package payment for items and services in the following seven categories into the payment for the services with which they are furnished:

1) guidance services;
2) image processing services;
3) intraoperative services;
4) imaging supervision and interpretation services;

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\(^4\) Id. at 42642. The study is available at www.cms.hhs.gov/reports/downloads/dalton.pdf.
\(^5\) Id.
\(^6\) Id. at 42643.
\(^7\) Id. at 42649.
5) diagnostic radiopharmaceuticals;
6) contrast media; and
7) observation services.8

The agency has not disclosed adequate detail regarding its proposal -- specifically, the data relating to which APCs the costs of packaged items and services will be assigned or the amount of these costs assigned to each APC. Without these details, CHI and other stakeholders cannot meaningfully analyze the agency’s proposal and comment on it. Accordingly, we urge CMS not to package these seven additional categories until the potential effects of expanded packaging are better understood and the agency is confident that beneficiary access to the newly packaged items and services will not be compromised. This view is consistent with the APC Panel's recent recommendation to exclude radiation oncology from the proposal to package guidance services as well as its recommendation to exclude from packaging imaging supervision and interpretation services, some observation, and radiopharmaceuticals costing more than $200 a day. We do not believe packaging should be expanded to any of the other categories of ancillary services until CMS has developed and implemented an adjustment for charge compression and has analyzed the cumulative effect of these two modifications.

In addition to the lack of data causing us concern, CHI believes that CMS' stated reasons for the need to increase packaging are flawed. First, CMS notes that there has been a “recent explosion of growth in program expenditures for hospital outpatient services paid under the OPPS,” and as a result, the agency wants to bundle more items and services in an attempt to create an incentive to provide care that is more efficient.9 CHI does not agree that growth in OPPS program costs necessarily will be reversed by more items and services being bundled. There are many other reasons that growth in the outpatient setting may be occurring. For example, the Medicare population continues to grow and these beneficiaries could be accessing their care in the more appropriate outpatient setting. Either the aging population or the more appropriate setting could cause an increase in outpatient services, and further bundling will not slow or stop either trend. In fact, if expanded packaging is not implemented properly, care could shift inappropriately to more costly settings or beneficiaries could be asked to return for additional hospital outpatient visits to obtain the care they need.

Second, CMS asserts that its packaging proposals will allow the agency to continue to collect the data it needs to set appropriate, stable payment rates in the future. Because current and future payment rates are calculated based upon past claims, CMS must collect complete and accurate data on the items and services provided in the hospital outpatient department if the agency is to maintain

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8 Id. at 42653.
9 Id. at 42649.
appropriate APCs with adequate payment rates. As we note above, our ability to
assess the adequacy of the proposed rates is limited by the lack of data provided by
CMS. We urge the agency to release this data as soon as possible and to delay
finalizing its packaging proposal until the potential effects of expanded packaging
are more fully analyzed and understood.

To the extent that the rates are appropriate, this likely occurred because
hospitals improved their coding in recent years, and CMS was able to analyze this
expanded claims data as a result. Unfortunately, hospitals rarely code for items
and services that are not separately paid. Thus, CMS may not have the benefit of
robust claims data in future years. To offset this probability, CMS should clearly
require hospitals to submit correct and complete coding for any items and services
the agency ultimately packages.

II. PROPOSED CHANGES FOR DEVICES

A. The rate-setting methodology for device-dependent APCs should ensure
stable payment rates and require hospitals to use C-codes. (OPPS: Device-
Dependent APCs)

CHI is concerned about the stability of OPPS rates for device-dependent
APCs, especially in light of the agency’s new proposals to expand packaging. We
are disappointed that CMS does not propose to set a floor to moderate for any
decreases in median costs from 2007 to 2008. In 2006, CMS adjusted median costs
for device-dependent APCs to the greater of the median from claims data or 90
percent of the payment median that the agency used to set the CY 2005 payment
rate.10 This payment floor helped provide a stable transition from 2005 rates and
prevented large decreases in payments from year to year. Without such a floor, the
median costs of one APC will decline more than 10 percent from 2007 to 2008.11
CHI is concerned that sizeable decreases in any individual device-dependent APC
tax rate will lead to unpredictability in reimbursement and create obstacles to
patient access to high-technology devices and procedures. We urge CMS to protect
beneficiary access to innovative devices by preventing large decreases in payments
for device-dependent APCs. CHI recommends that CMS establish a payment floor
for CY 2008, and we ask that CMS exercise caution when making any cuts in
payment for device-dependent APCs.

CMS can set accurate payment rates only if it has accurate data on hospitals’
costs. For device-dependent APCs, CMS needs claims data that include the correct
codes to identify the devices used. Use of accurately coded claims will lead to better
estimates of costs for device-dependent APCs than simply using all claims,
including those that do not include correct coding for the device. To help CMS

10 Id. at 42719.
11 Id. at 42720.
gather essential data for rate setting, we recommend that the agency make payment for device-dependent APCs only when the hospital includes an appropriate C-code identifying the device used.

Although CHI supports the use of only correctly coded claims in setting APC payment rates, we note that it often takes a few months for hospitals to implement new C-codes, particularly if the hospital has not reliably used those codes in the past. As a result, it may take a year or two after CMS issues a new C-code for the Medicare claims data to reflect use of and appropriate charge for the device. CHI urges CMS to consider this data lag when determining whether claims data is available to calculate appropriate rates. We believe that at least two full years of data is necessary to set appropriate rates for devices and device-dependent APCs.

B. The New Technology APC and pass-through application processes and the transition of technologies to clinical APCs should be more consistent and transparent. (OPPS: Expiring Device Pass-Through Payments; New Technology APCs)

Appropriate use of New Technology APCs and pass-through status are essential to protecting beneficiary access to advanced therapies. Congress created these provisions to ensure that hospitals receive appropriate reimbursements while CMS collects data for use in future APC assignments and rate setting. However, we remain concerned that that the application processes for pass-through status and new technology APC assignments are not transparent or predictable.

First, the CMS website does not provide information on the technologies for which New Technology APC assignments or pass-through status is sought, nor does it provide information regarding the number of applications received. In contrast, CMS provides this information regarding applications for new technology add-on payments under the inpatient prospective payment system (IPPS). Second, CMS’ consideration of applications remains vague. The agency does not provide information about the rationale for accepting or denying an application, does not accept public comment on its decisions, and provides no information about the timeliness of decision-making for completed applications.

Because CMS considers these applications privately, stakeholders often do not understand the agency’s decisions. We also cannot confirm whether CMS’ decisions are correct. For example, if CMS assigns a new Current Procedural Terminology (CPT) code to a clinical APC instead of to a new technology APC, stakeholders will not know whether CMS considered all of the relevant evidence before making that decision. We cannot be confident that CMS is using all of the options under the statute to protect beneficiary access to new technologies unless the agency makes its processes and decision-making more transparent.
CHI believes that sharing information about applications for New Technology APC assignments and pass-through status will help stakeholders understand the process better and ensure that these statutory protections for new technologies are used appropriately. Additionally, as the agency moves towards greater bundling and packaging of items and services, accurate and detailed information regarding the process for New Technology assignments is paramount. Accordingly, CHI encourages CMS to provide opportunity for public discourse as it currently does with the new technology add-on process in the IPPS, explain its rationale for its decisions, and publish its timelines for decision-making.

CMS also could improve the predictability of New Technology APC assignments by implementing the APC Panel’s August 2006 recommendation “that when CMS assigns a new service to a New Technology APC, the service should remain there for at least two years until sufficient claims data are collected.” The purpose of new technology APCs is to protect beneficiary access to advanced treatment options while CMS collects sufficient data to set appropriate rates. CMS often moves services from new technology APCs to clinical APCs after less than two years. These moves may be premature and deny the agency the opportunity to gather sufficient data. Hospitals often cannot update their billing systems to use the new codes required for assignment to new technology APCs until several months after CMS issues the codes. This delay prevents CMS from beginning to collect accurate claims data until months into a technology’s first year in a new technology APC. By ensuring that all assignments to New Technology APCs last at least two years, CMS would improve its ability to collect a sufficient number of accurate claims to set appropriate rates in the future.

C. CMS should use external data to ensure rates for device-related APCs are appropriate. (Device-Dependent APCs)

CHI believes it is critical for CMS to use the best available data in setting rates. For many items and services, CMS’ own data may be sufficient to calculate appropriate payment rates, but some items, particularly new technologies, are not adequately represented in claims data for CMS to accurately determine costs and set appropriate rates. CHI agrees with last year’s APC Panel’s recommendation that CMS should use readily available external data to validate costs determined by CMS’ claims data. Such external data can be used in three key areas: (1) to verify whether CMS’ proposed rates are appropriate when the agency proposes to make a significant cut in reimbursement, (2) to identify and adjust payment for technologies that have been under-reimbursed in the past, and (3) to remedy the effects of charge compression on reimbursement rates.

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13 Id.
CMS should permit manufacturers to present confidential data to the agency in support of their case for more adequate payment. CMS should incorporate this supplemental data into the median cost calculations to set appropriate APC weights. Appropriate rates help ensure beneficiary access to these important therapies.

In addition to strongly recommending that CMS accept and use external data to ensure that its payments are appropriate, we urge the agency to establish protections for the confidentiality of such data. Manufacturers and hospitals will not provide the data CMS needs to establish accurate rates unless they are assured that the data will not be shared with others. These stakeholders also may be bound by non-disclosure agreements that prohibit them from sharing data with CMS if the agency does not agree to protect it. We ask CMS to maintain the confidentiality of external data submitted for ratesetting and to include this assurance in the final rule.

III. PROPOSED PAYMENT CHANGES FOR DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS

A. Reimbursement for drugs under the OPPS should be no less than ASP plus six percent. (OPPS: SPECIFIED COVERED OUTPATIENT DRUGS)

Presently, CMS reimburses most drugs at ASP plus six percent in both the physician’s office and the hospital outpatient setting. For separately payable drugs without pass-through status in the OPPS, CMS has proposed to decrease the rate to ASP plus five percent.\textsuperscript{14} CHI is troubled by this proposed reduction because many hospitals already are struggling to provide care when drugs are reimbursed at ASP plus six percent. In the past few years, hospital outpatient departments have faced significant reductions in payment for drugs, with no adjustment for pharmacy service costs, and have experienced increasing patient loads. In particular, in addition to treating Medicaid patients and the uninsured that often are not treated in physicians’ offices, hospitals are taking on increasing numbers of patients without supplemental insurance.

Additionally, hospitals face new statutory and regulatory mandates by the National Institute for Occupational Safety and Health (NIOSH), the Occupational Safety and Health Administration (OSHA), and states that increase the cost of handling and disposing of drugs. In this environment, CHI is concerned that the current reimbursement rate of ASP plus six percent may not be sufficient to guarantee the availability of appropriate therapies to beneficiaries and that a reduction in payment to ASP plus five percent further will encumber hospitals that currently are struggling to supply drugs to patients. Medicare beneficiaries will be

\textsuperscript{14} 72 Fed. Reg. at 42736.
left without providers for treatment unless hospitals receive sufficient payment for providing care.

In addition to not being adequate to cover hospitals’ drug acquisition costs, CMS’ proposed rates are not sufficient to cover hospitals’ pharmacy service and handling costs. In its June 2005 report, MedPAC stated that 26 to 28 percent of direct costs for pharmacy departments were comprised of pharmacy department wages, salaries, fringe benefits, and supplies. Assuming that all hospitals could purchase covered drugs at ASP, overhead costs of 28 percent would lead to hospital acquisition and handling costs of ASP plus 39 percent.

Pharmacy services cover a wide range of activities from basic mixings and reconstitutions to more advanced compounding that require a clean room, trained and certified personnel, and ancillary supplies. Pharmacists and pharmacy technicians perform a variety of services including conducting quality assurance measures to ensure therapies are correctly prepared, safely disposing of any unused medications, and consulting with physicians about the most suitable selection, dosage, and administration of drugs. Pharmacists cannot bill separately for any of these services, and yet these activities require significant labor and resources, and, without them, the likelihood of error is substantial. The costs related to the provision of such services include pharmacist and pharmacy technician salary and benefits, supplies, equipment, and facility upgrades necessary required to satisfy changes in pharmacy regulations. Medicare payment for all aspects of providing drugs, including preparing drugs, performing quality control, and administering drugs, must take into account all of these factors. Providing adequate reimbursement for drugs will ensure that hospitals can continue to provide high quality of care.

We believe CMS’ calculations that led to the proposed rates are based on several incorrect assumptions and analyses. Specifically, as discussed in greater detail above, because hospitals usually increase charges for high cost items by a smaller percentage than low cost items, CHI believes the imposition of a constant CCR to pharmacy incorrectly estimates the costs for specific drugs. When a single CCR is applied to these items, the estimated cost of the low cost drug could surpass its actual cost. In contrast, when a single CCR is applied to a higher cost item, the resulting charge may be below its actual cost. Consequently, estimated unit costs and the Medicare payment rates based on such costs are unrelated to the actual costs of specific drugs. The RTI report discussed above provides further support for this conclusion. This is why implementing an adjustment to account for charge compression in the OPPS as soon as possible is critical for appropriate OPPS rate-setting.

CMS also underestimated the overhead costs when it used the mean unit costs for only separately paid drugs in the estimate of the total costs for drugs compared to the total costs using ASP. In its June 2005 report, MedPAC noted that most hospitals do not set charges for handling costs and lack precise information about the magnitude of these expenses.\textsuperscript{17} To the extent that hospitals include pharmacy service and overhead costs in their charges for drugs, a disproportionate amount of those costs are included in the charges for lower cost drugs due to hospitals’ differential markups. Because the agency excluded from its calculations the lower cost drugs that are not separately paid under the OPPS, it also excluded a significant portion of hospitals’ charges for pharmacy service and overhead costs.

We believe CMS could estimate overhead costs more accurately if it included all drugs with HCPCS codes in its calculations of mean unit cost. Although the exact share of total pharmacy service and handling costs assigned to each therapy might not be accurate, including all HCPCS-coded drugs would allow CMS to account for most of a hospital’s handling charges. Industry analysis found that including HCPCS-coded packaged drugs with reported ASPs in the calculations of mean unit cost increased these estimates to more than ASP plus 14 percent. CMS could account for yet more pharmacy overhead if it included the numerous low cost drugs without HCPCS codes or ASPs that have charges reported under general pharmacy department revenue codes. Unless CMS includes, at a minimum, the packaged drugs with HCPCS codes with ASPs in its calculations, it will not accurately capture pharmacy service and handling costs.

CHI encourages CMS to explore methods of capturing a greater proportion of pharmacy service and handling costs in its calculations. Until CMS develops an appropriate way to reimburse hospitals for pharmacy service and handling costs and adjusts its rate-setting methodology for charge compression, however, CHI urges CMS to set payment for drugs at no less than ASP plus six percent. This is consistent with the recommendation made by the APC Panel at its March and September 2007 meetings.

B. CMS should continue to work with stakeholders to develop suitable methods of reimbursing hospitals for pharmacy service and handling costs and not require hospitals to report pharmacy overhead charges on an uncoded revenue code line as proposed.

As explained above, CHI believes that the claims and cost report data are insufficient to determine accurate payments for the acquisition and handling costs for each drug. Additionally, we believe that instructing hospitals to report the

\textsuperscript{17} MedPAC, Report to the Congress: Issues in a Modernized Medicare Program, June 2005, at 139-140.
pharmacy overhead charge on an uncoded revenue line only will increase administrative burdens for hospitals without generating quality data that could be used for future rate setting. Therefore, similar to the recent recommendation of the APC Panel, we urge CMS not to implement this instruction.

CMS’ proposal presents many administrative burdens for hospitals without the potential for accurate data to offset these challenges. For example, this instruction would require hospitals to set charges for many drugs and implement hundreds of changes to their systems before the end of this year. In addition to these costly programming changes, hospitals would have to make substantial investments in performing time and motion studies to determine the appropriate overhead charge for each drug. Even if hospitals could make these changes, there is no assurance that the data would be useful to CMS because the agency permits hospitals to decide whether to report a charge per drug or per episode of drug administration services. Therefore, the data CMS would receive would not necessarily identify the overhead charges associated with any particular drug and would not be appropriate to use as the basis for packaging payment for these services into payment for other procedures.

Instead of proceeding with its proposal to report pharmacy overhead using the uncoded revenue code line, CHI urges CMS to implement the three phase plan recommended by the APC Panel at its March 2007 meeting. This plan, similar to the one developed by a group of stakeholders, involves automatic payments for pharmacy services and overhead costs based on three separate levels of complexity in addition to reimbursing for acquisition costs for drugs at ASP plus six percent. In phase one, the agency would assign all drugs with HCPCS codes to one of the three pharmacy services categories and pay the pharmacy services amount automatically each time a hospital billed a HCPCS-coded drug. Then, in phase two, CMS would use various governmental reports and outside data to set reimbursement rates for the three pharmacy services categories. In phase three, CMS would establish payments for pharmacy services and overhead costs based on claims data as it does for most other items and services in the OPPS.

Should CMS decide not to pursue the three phrase approach, the agency also could explore a consolidated two-phase plan that omits the use of survey data. Phase one would be the same as the first phase described above. In phase two,

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18 72 Fed. Reg. at 42735.
19 Id.
21 Id. Specifically, CHI recommends that CMS refer to the Government Accountability Office (GAO) and MedPAC reports that estimate pharmacy services and overhead costs.
22 Id.
however, hospitals only would receive the pharmacy services payments if they reported the respective charges and costs associated with each drug.

Both of these plans have a more minimal administrative burden on hospitals because rather than setting unique charges for each individual drug, hospitals would only need to set charges for the three categories described above. Moreover, each would include an initial phase where pharmacy services payments would be made automatically and would give hospitals adequate notice before requiring them to set charges. CHI understands that hospitals would need at least a year to revise their chargemasters and billing systems to implement this change, and they also would need detailed guidance from the agency on these issues. For example, hospitals would require further guidance from CMS on the specific items and services to include when setting charges, processing crossover claims, and complying with uniform charge requirements. We believe that as long as the charge for the drug plus the charge for pharmacy services equals the charge to other payers for the drug with the overhead combined, the uniform charge requirement will be met. In order for CMS to receive accurate and appropriate data, the agency must provide specific and detailed directions to hospitals well in advance of implementation.

CHI believes that these proposals are consistent with the goals of packaging and of a prospective payment system. Regardless of the plan, we believe that payment for pharmacy services and overhead costs still should be packaged into the payment for the drug by automatically linking the appropriate pharmacy services and handling code to the individual HCPCS code for the drug, minimizing the administrative burden for hospitals. Our proposals allow for accurate reimbursements for pharmacy overhead and handling costs, minimize administrative burdens, and maintain the goals of having these payments packaged. CHI strongly encourages CMS to continue to work proactively with stakeholders to develop suitable methods of reimbursing hospitals for pharmacy service and handling costs. CMS should not adopt any payment reductions for drugs until such a method is developed.

C. CMS should eliminate the bundling threshold and pay separately for all drugs with HCPCS codes as it does in the physician office setting, including all radiopharmaceuticals and contrast agents.

CHI continues to believe that paying separately for all drugs with HCPCS codes is the best way to ensure hospitals are reimbursed appropriately for all the drugs they provide. Although we acknowledge that this change in policy is inconsistent with CMS’ desire to expand packaging and to increase the packaging threshold from $55 per day to $60,23 we believe it is a simple way for CMS to act

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23 Id. at 42732.
immediately to improve reimbursement while working on more permanent solutions for charge compression and paying adequately for pharmacy services and handling. Because a disproportionate share of overhead is distributed to lower cost, packaged drugs, we believe that paying for these drugs separately and including them in CMS rate-setting methodology will make the rates more adequate for all drug therapies.

Currently, the OPPS packaging policy discourages hospitals from using packaged therapies even though they may be the most clinically suitable. Paying separately for these therapies will remove these incentives and would help provide hospitals with appropriate payment for drugs provided in their outpatient departments. Because hospitals are strongly encouraged to code for these drugs currently, there should be no additional administrative burden on hospitals by separately reimbursing these drugs. As discussed below, separate reimbursement would also improve the accuracy of payments for hospitals administering concurrent infusions for packaged drugs in the event that CMS does not revise its proposal to allow hospitals to bill for concurrent infusions.

Moreover, separate payment is comparable to physician reimbursement in the office setting. CMS has previously indicated its concern that differences in payment methodologies should not shift beneficiary care from one setting to another. These shifts are the natural result when only certain drugs are paid separately at ASP plus five percent in the hospital outpatient department; however, all drugs with HCPCS codes are reimbursed at ASP plus six percent in the physician office.

Paying for HCPCS-coded drugs separately also is consistent with the objectives of the President’s Executive Order 13410 to promote quality and efficient health care in government sponsored health care programs. This order’s goal is to empower beneficiaries to make price comparisons in order to spend their health care dollars more wisely. Unfortunately, making comparisons regarding drug administration in physician offices and hospital outpatient departments is difficult, if not impossible, for beneficiaries because CMS proposes to bundle drugs less than $60 in the HOPPS. This problem is exacerbated to the extent that private payers adopt these packaging and payment methodologies. CHI believes that the goals of the transparency initiative would be better served if there were more consistency with the physician office setting and CMS paid separately for all drugs with HCPCS codes.

CHI applauds CMS’ proposal to continue to pay separately for all oral and injectable forms of 5HT3 anti-emetics.24 We agree that payment rules should not impede treatment choices made by physicians and patients. In fact, this is precisely

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24 Id. at 42733.
why we believe the packaging threshold would be eliminated for all HCPCS-coded drugs, including contrast agents and radiopharmaceuticals. We believe that doing so would improve the accuracy of OPPS rates for all services in which drugs are used, promote correct coding without increasing hospitals’ administrative burdens, be more comparable to physician reimbursement in the office setting, and would improve the data upon which future rates are set.

D. CMS should not apply an equitable adjustment to any drugs.

CHI supports the continuation of a market-based reimbursement policy using the ASP-based methodology for all therapies. We believe this is in line with Congress’ intent in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). CMS’ decision not to include a proposal to adjust payment for one drug based on another drug will let the market, not arbitrary government price setting, decide the most suitable payment for therapies. We commend CMS for this decision and encourage CMS to not impose an equitable adjustment to any drug in the final rule. We ask the agency to clarify that it will not change its current position regarding the use of equitable adjustment for any drug without first giving the public an opportunity to comment through the rulemaking process.

E. CMS should analyze potential edits to correct claims data for radiopharmaceuticals and continue to use the current payment methodology for radiopharmaceuticals in the meantime.

CHI believes that CMS’ proposed approach to setting payment rates for radiopharmaceuticals violates current law and will result in inaccurate payments that may impede beneficiary access to care. The statute requires that all radiopharmaceuticals be treated as specified covered outpatient drugs to be reimbursed at their average acquisition cost with adjustments for pharmacy services and overhead. Yet this is inconsistent with CMS’ proposal to package diagnostic radiopharmaceuticals and therapeutic radiopharmaceuticals that have a per day cost of $60 or less and to pay for higher cost therapies based on CMS’ usual rate-setting methodology. Accordingly, CHI asks that CMS analyze potential edits to correct claims data for radiopharmaceuticals and continue to use the current payment methodology in the meantime. The APC Panel also recently recommended that CMS pay for radiopharmaceuticals using the current methodology but also recommended packaging for diagnostic radiopharmaceuticals less than $200. Again, we do not believe that additional packaging is appropriate and instead assert that all drugs with HCPCS codes, including radiopharmaceuticals, be paid separately.

CHI is particularly concerned about CMS’ proposed approach to setting payment rates for therapy-related radiopharmaceuticals. Therapy-related
radiopharmaceuticals include both the diagnostic and therapeutic products approved by the Food and Drug Administration (FDA) as an integral part of the therapeutic regimen. The Proposed Rule would package payment for all diagnostic radiopharmaceuticals and set a prospective payment rate for therapeutic radiopharmaceuticals based on mean costs.\textsuperscript{25} CHI is very troubled because the proposed CY 2008 payment rates are almost the same, or lower, than the rates in last year’s proposal. Of further concern is that these rates do not capture the considerable pharmacy service and overhead costs of providing the therapy -- the radiopharmacy compounding fee, for example. Rather than basing payments on mean charges reduced to cost and failing to include all of the costs of providing a therapy, CMS should continue to use the methodology it implemented in 2006 until it can analyze potential edits to correct claims data. In addition, we ask CMS to continue to work with stakeholders to develop a payment methodology for therapy-related radiopharmaceuticals that appropriately captures all of the costs of the therapy and addresses charge compression.

**F. CMS should continue to pay separately for contrast agents.**

Similarly, CHI is concerned that CMS’ proposal to package payment for all contrast agents into payment for the associated diagnostic or therapeutic procedure will harm Medicare beneficiary access to certain procedures.\textsuperscript{26} Because CMS does not use an accurate methodology for determining the acquisition cost of drugs, we believe that CMS is also not accounting for the full costs of these products in its proposals. If this proposal is finalized, hospitals using contrast imaging drugs when medically necessary, will incur costs for the contrast imaging drugs and their administration without receiving any incremental payment beyond the payment for the procedure without contrast. As discussed in depth above, CHI believes that all drugs with HCPCS codes -- including radiopharmaceuticals and contrast agents -- should be paid separately under the OPPS.

**G. The agency should continue to pay pre-administration-related services for IVIG at the 2007 rate and create a new permanent add-on payment to ensure beneficiary access to this critical treatment.**

CHI urges CMS to reconsider its proposal to transition payment for pre-administration services from a new technology APC to a clinical APC because of the significant reduction in reimbursement. Currently, CMS reimburses hospitals $75 for pre-administration services. Because of the transition, this rate will drop to $39, an approximate fifty percent reduction.\textsuperscript{27} As you are aware, changes to Medicare’s payment methodologies for drugs have raised concerns over beneficiary access to

\textsuperscript{25} Id. at 42738.
\textsuperscript{26} 72 Fed. Reg. at 42672.
\textsuperscript{27} Id. at 42705.
IVIG. CHI believes CMS recognized the unique aspects of this therapy and its importance to Medicare beneficiaries by establishing a payment for pre-administration-related services for IVIG in last year’s OPPS final rule. Regrettably, CMS now proposes a dramatic reduction to this payment for 2008, and we believe this would be a major step backward. All of the costs hospitals incur related to IVIG that CMS identified historically will continue to be incurred next year, and CMS offers no evidence that these costs would not continue.

In addition to maintaining these payments for IVIG, CHI urges CMS to establish an additional payment to protect beneficiary access to IVIG, modeled after the blood clotting factor add-on. The permanent add-on payment for blood clotting factor resulted from a January 2003 Government Accountability Office (GAO) report and subsequent Congressional activity in granting the Secretary the authority to establish this add-on payment. CHI believes that a recent OIG report on IVIG provides the same evidence for IVIG as the January GAO report did for blood clotting factor and that the Secretary should provide for a permanent add-on payment for IVIG accordingly. Specifically, the recent OIG report states that only 56 percent of the IVIG sales to hospitals by the three largest distributors occurred at prices below the Medicare payment amounts.\(^{28}\) CHI expects this trend to continue and asks that CMS, in addition to maintaining current reimbursement levels for IVIG and pre-administration-related services, also establish a permanent additional payment.

H. CMS should be cautious when considering which drugs no longer qualify for pass-through payments.

The Social Security Act specifies that pass-through payments for drugs may be made for no less that two years and no longer than three years.\(^{29}\) For 2008, CMS proposes to eliminate the pass-through status of seven drugs based on this criteria. CHI urges CMS to be cautious when considering which drugs no longer qualify for pass-through status. Sometimes there are circumstances that may have prevented a drug from being marketed that will influence whether the statutory timeframe has been exhausted.

For example, CHI believes that CMS’ proposal to remove the pass-through status for natalizumab is incorrect as this therapy, due to unique circumstances, is still eligible for pass-through status under the statute. In April of 2005, natalizumab was granted pass through status by CMS. One month earlier, however, the therapy was voluntarily withdrawn from the market and did not return until July 2006, tolling the time from April 2005 to July 2006. Because no patients received this therapy during the 17.5 months that the therapy was not on

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\(^{28}\) Id.
\(^{29}\) SSA § 1833(o)(6)(C)(i).
the market, CHI believes that this time should not count towards the calculation of pass-through status. As a result, natalizumab is still eligible for pass-through status, and we ask that CMS to maintain pass-through status for it.

I. The agency should pay for concurrent infusions, particularly if it continues to package lower cost drugs.

Although physician offices are paid to administer concurrent infusions, hospital outpatient departments are not. This is particularly troubling because lower cost drugs are packaged in the OPPS. Thus, when administering a concurrent infusion for a packaged drug, the hospital is paid neither for the drug nor the administration service. At its March 2007 meeting, the APC Panel sought to remedy this situation by recommending that CMS pay separately for concurrent infusions of drugs under CPT code 90768 at the same time as sequential infusions under CPT code 90767. Unfortunately, CMS disregarded the advice of the Panel and instead decided to continue to package payment for 90768 into payment for other drug administration services because it determined that the costs of concurrent infusions already are represented in the claims data.30 We think this is unlikely. In the absence of clear data establishing that these services are appropriately reimbursed in hospital outpatient departments, we ask CMS to protect access to these services by providing separate payment under the OPPS. This also will create greater parity with the physician office setting.

IV. CONCLUSION

CHI appreciates the opportunity to offer these comments. We look forward to working with CMS on these and other issues of concern in the future. If you have any questions or would like to discuss these ideas further, please contact Todd Gillenwater at 858-551-6677.

Respectfully submitted,

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