June 13, 2008

THE
CATHOLIC HEALTH
ASSOCIATION
OF THE UNITED STATES

Honorable Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

REF: CMS-1390-P

RE: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2009 Payment Rates; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules; Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians.

Dear Mr. Weems:

The Catholic Health Association of the United States (CHA) is pleased to submit the following comments on the notice of proposed rulemaking (NPRM) RE: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2009 Payment Rates; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules; Proposed Collection of Information Regarding Financial Relationships Between Hospitals (*Federal Register*, Vol. 73, No. 84) published April 30, 2008.

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MS-DRG Documentation and Coding Adjustments

The proposed FY 2009 hospital inpatient prospective payment (IPPS) rule includes the documentation and coding adjustments required by the TMA, Abstinence Education and QI Programs Extension Act of 2007 (P. L. 110–90). The statutory adjustment reduces the national standardized amounts by an additional -0.9 percent in FY 2009 on top of the -0.6 percent adjustment applied to the standardized amounts in FY 2008, yielding a combined reduction of -1.5 percent. P. L. 110–90 also specifies that to the extent the documentation and coding adjustments applied in FY 2008 and FY 2009 result in overpayments or underpayments relative to the actual amount of documentation and coding-related increases, the Secretary of Health and Human Services ("Secretary") will correct the overpayments or underpayments in fiscal years 2010-1012.

CHA is extremely concerned about the recoupment that the law specifies for fiscal years 2010-2012. Determining how much of the total increase in case-mix is due to changes in documentation and coding will be difficult and, if this determination is not made appropriately, could result in overly large reductions to the standardized amount

which would be disruptive to hospitals. CHA applauds the Centers for Medicare & Medicaid Services (CMS) for recognizing the importance and challenges of this task by describing its preliminary analysis plans in the FY 2009 proposed rule and inviting public comment.

CMS plans to conduct a thorough retrospective claims analysis to measure change in case-mix for FY 2008 and FY 2009 and to attribute a portion to underlying changes in actual patient severity and a portion to documentation and coding improvements under the Medicare Severity Diagnostic Related Group (MS-DRG) system. CHA supports this part of the analysis plan and believes that it could provide useful information about how much of the overall case-mix increase may be related to documentation and coding changes.

CMS also plans to evaluate retrospective claims data to identify the specific MS-DRGs and diagnoses that contributed significantly to the within-MS-DRG case-mix increase. This analysis may provide valuable information about the MS-DRGs experiencing the greatest case-mix change, but we emphasize that not all of the increased incidence of secondary diagnoses within a base MS-DRG can be attributed to changes in documentation and coding. A portion of the increase likely will be real.

Finally, if additional analyses are warranted, the proposed rule states that CMS may decide, if feasible, to use historical data from the Hospital Payment Monitoring Program (HPMP) to corroborate the within-base MS-DRG shift analysis. The HPMP is supported by the Medicare Clinical Data Abstraction Center (CDAC). CHA believes that the CDAC data, because it includes a statistical sample of medical records over several years, could provide the best data source to evaluate case-mix change. In the proposed rule, however, CMS does not commit to using these data.

CHA observes that none of the analyses described in the proposed rule will answer the question of how much of the total case-mix change is due to documentation and coding. P.L. 110-90 specifies that the adjustments in 2010-2012 will be based on the Secretary's estimate of case-mix increase that "implementation of MS-DRGs resulted in changes in coding and classification that did not reflect real changes in case-mix." To the extent that policy changes, like the MS-DRG classification system itself and the related grouper, contributed to the increase in the case mix index (CMI), we believe that the law requires this portion to be considered the result of CMS actions rather than hospital behavior. Consequently, this policy-related portion should not be subject to recoupment.

CHA is also concerned that, based on history, CMS might develop the estimate of the documentation and coding-related increase as a residual. That is, the agency might reduce the overall increase in the case-mix index by an estimate of real case-mix change and assume that the residual is the result of documentation and coding. CHA believes that this is not an accurate method for determining coding-related increases. Many factors can contribute to case-mix change and careful analysis is required to determine the contribution of each factor. Changes in medical practice, demographics and health status over time affect case mix growth. In addition, any change in patient population or medical practice that changes the distribution of patients across MS-DRGs can affect the amount of case-mix change by shifting volume to higher or lower weighted MS-DRGs or causing some MS-DRGs to experience more rapid volume growth than others over time.

In addition, more sudden shifts in case mix can occur because of specific policy changes. A host of significant policy changes by CMS co-occurring with the implementation of MS-DRGs has likely accelerated the growth rate in the CMI. These include: the implementation of present on admission coding changes; the Recovery Audit Contractor (RAC) program, which includes incentives to shift low acuity patients to the ambulatory setting; the implementation of the Medicare Part D program, which has resulted in an acceleration of the movement away from the fee-for-service program and the CY 2008 dramatic changes in the criteria for what can be done in an Ambulatory Surgery Center (ASC), which will accelerate the move of lower acuity patients to the outpatient setting, again resulting in increased acuity in the inpatient setting. Other policy changes include the implementation of cost-based weights, the MS-DRG classification system and grouper, changes in outlier policy, and changes in post acute transfer policy.

Although the analysis plan described in the FY 2009 proposed rule is a good start, CHA believes it is insufficient to evaluate and quantify the various sources of coding change. It does not reflect the methodological rigor used in the work that CMS has cited on numerous occasions (such as the RAND Corporation) as providing the best estimate of how much case-mix change is due to real changes in case-mix and how much is due to changes from coding and documentation.

As described in the FY 2009 proposed rule, the 1999-2007 CDAC data sample, which includes medical records in addition to claims data, provides an important opportunity to replicate the RAND methodology using contemporary data.

We strongly urge CMS to pursue a replication of the RAND case-mix analyses using the CDAC data. While we recognize that considerable resources might be required to undertake this work, it is critical to have the best case-mix measurement possible to ensure payment accuracy.

Preventable Hospital-Acquired Conditions (HACs) Including Infections

CMS proposes to add nine additional HACs to the existing eight for which the agency will pay the lower MS-DRG amount if the complication was acquired at the hospital and the patient has no other complications or comorbidities. While we are pleased that CMS continues to demonstrate its commitment to improving the quality of patient care and believe CMS is moving in the right direction, care should be taken that the timeline is not overly aggressive.

There are still steps that need to be taken such as amassing the evidence base, disseminating the practice guidelines, working with clinicians to accept such guidelines, creating new codes, changing coding guidelines and training coders before this new policy can be fully operational. We are concerned that CMS is trying to force the adoption of an aggressive policy without the requisite infrastructure.

The agency was only required to choose two measures for implementation in FY 2009, and yet it chose eight measures. Now, CMS is looking to expand the list for FY 2009 to possibly 17 measures after hospitals thought the list was finalized. Giving hospitals only two months to prepare for coding and documenting additional conditions is an unreasonable timeline. Moreover, CMS has yet to test and validate the HACs previously chosen to inform next steps and avoid "unintended consequences."

CHA believes that CMS should create a standardized adoption framework including a timeline that will ensure that conditions included in this policy are truly preventable, are rational, and do not result in unintended consequences, and that hospitals have the necessary practice guidelines and sufficient warning before implementation. It is also critically important that CMS focus on establishing reasonable prevention rates for certain conditions and narrow the target patient population.

CHA is particularly concerned that the CMS-cited literature indicates that most of the proposed conditions are not preventable 100 percent of the time. In addition, the majority of the proposed conditions lack definitive and scientifically proven prevention guidelines on which hospitals can act to improve care. Thus, tying payments to these conditions that have a non-zero prevention rate and no associated actionable guidelines is unfair to hospitals and misleading to consumers.

CHA only supports the inclusion of S*taphylococcus aureus Septicemia* as a HAC, but for FY 2010, not FY 2009 as proposed by CMS because of the unreasonable time frame for hospitals to implement.

While CHA strongly believes that *Ventilator-Associated Pneumonia, Clostridium difficile-*Associated Disease, *Surgical Site Infection* following certain elective surgeries, *Deep Vein Thrombosis/Pulmonary Embolism, Legionnaires' Disease, Iatrogenic Pneumothorax, Glycemic Control,* and *Delirium* are serious conditions with a negative impact on patient care, we do not support inclusion of these conditions in FY 2009. Rather, CHA urges CMS to coordinate with other agencies such as the Centers for Disease Control and Prevention (CDC) and other stakeholders to conduct thorough analysis and field testing to validate these measures ensuring there are clear scientific and measurable prevention guidelines for hospitals to effectively implement, and reasonable prevention rates are set.

For example, *Clostridium difficile* is an anaerobic, spore-forming bacillus that is responsible for a wide gamut of *Clostridium difficile* associated diseases including, uncomplicated diarrhea, pseudomembranous colitis, toxic megalcolon, and may lead to overwhelming sepsis and death. Even though *Clostridium difficile* is the most common cause of hospital associated diarrhea, more than 90% of the cases occur after or during antimicrobial therapy. Diarrhea is in fact listed as an adverse effect with almost any antibiotic choice. Many patients present to healthcare facilities after being treated with antibiotics as an outpatient.

In addition, patients who are admitted with any type of infectious illness that requires antibiotic therapy would be appropriately treated with this therapy. Because appropriate use of antibiotics may cause hospital associated diarrhea/*Clostridium difficile*, the requirements for payment reduction in these cases would be inappropriate.

As part of its HAC payment provision, CMS proposes that conditions identified as an "N" (not present on admission) or "U" (medical record documentation is insufficient to determine whether condition was present on admission) would not receive higher payment. CHA is concerned about this proposal because adoption of the present-on-admission indicators is still relatively new and hospitals continue to learn how to report these indicators properly (for example, distinguishing between a "U" and a "W" (not possible to determine when onset of condition

occurred)). We urge CMS to apply the HAC payment policy only to those conditions coded as an "N." CMS should conduct an assessment of the frequency of the use of the "U" option before making a decision to apply this policy to conditions so coded.

Proposed Changes to the Hospital Wage Index.

Proposed revision of the reclassification of average hourly wage comparison criteria.

CHA is opposed to increasing the test a hospital must meet in order to qualify for geographic reclassification. Currently an urban hospital that is seeking geographic reclassification must demonstrate that its average hourly wage is at least 108 percent of the average hourly wage of hospitals in the area in which the hospital is located and at least 84 percent of the average hourly wage of hospitals in the area to which it seeks redesignation. The urban criteria were set in 1993.

The applicable criteria for rural hospitals, which were set in the FY 2000 IPPS final rule, are 104 percent and 82 percent respectively. CMS said that the reduced reclassification criteria for hospitals located in a rural area were "determined to allow a significant benefit to some hospitals that were close to meeting the existing criteria but would not make the reclassification standards overly liberal for rural hospitals."

CMS said that it had ran simulations with more current wage data to determine what would be the appropriate average hourly wage criteria. Not surprisingly this simulation showed a change in the relationship of a hospital's average hourly wage to its wage area. As a result, for urban hospitals, CMS proposes to retain the percentage applicable to the urban area in which the hospital is located but to increase the percentage from 84 percent to 88 percent of the average hourly wage of hospitals in the area to which it seeks redesignation. And while maintaining the 104 percent criterion for rural hospitals, CMS is proposing to increase the criterion from 82 percent to 86 percent of the average hourly wage of hospitals in the area to which it seeks redesignation.

While CHA understands the percentage test of a hospital as regards the area in which the hospital is located, CHA does not understand, nor has CMS tried to explain, the relationship between a hospital's average hourly wage compared to the average hourly wage of hospitals in the area to which it seeks reclassification. This appears as a completely arbitrary percentage.

The fact that increasing the above percentage test may deny geographic reclassification to more that 15 percent (an estimate made by CMS) of the applicants raises the question of the type of facility adversely impacted by this proposed decision. How many of the potential losers are rural or otherwise isolated facilities? How many are rural referral centers? These facilities are struggling and any further damage to their economic prospects could be quite damaging. The same rationale that led CMS (then known as the Health Care Financing Administration) to reduce the qualifying criteria for rural hospitals in 2000 is still very much applicable today.

Proposed within-state Budget Neutrality Adjustment for the Rural Floor.

CHA is opposed to the proposal that would apply the budget neutrality adjustment on a state-by-state basis instead of across all hospitals. Budget neutrality only makes sense when such an

adjustment is spread across all hospitals. This is because budget neutrality is used throughout the Medicare program to ensure that certain payment adjustments do not increase overall Medicare spending. The adjustment is applied to all hospitals in recognition of the need to minimize the hospital-specific impact of the respective payment adjustment. Currently there is no statutory or regulatory state-specific budget neutrality adjustment.

Proposed Change to the Post-Acute Transfer Policy

CMS proposes to revise the post-acute care transfer policy as it applies to patient transfers to home health agencies. In particular, CMS proposes to extend the day threshold for patients who received home health services for a condition related to the hospital stay within three days of discharge to within seven days of discharge.

CHA opposes the proposed expansion of the post acute transfer policy as it undercuts the basic principles and objectives of the IPPS which is based on a system of averages. Cases with higher than average lengths of stay tend to be paid less than costs, while cases with shorter than average stays tend to be paid more than costs. An expansion of the transfer policy makes it unlikely that hospitals will break even on patients that receive post-acute care after discharge. Hospitals "lose" whether a patient is discharged prior to or after the average length of stay.

Outlier Payments

CMS proposes outlier thresholds for FY 2009 that will yield outlier payments equal to 5.1 percent of operating DRG payments and 5.73 percent of capital payments. Independent analyses, however, reveal that the proposed capital outlier threshold would approximate 5.37 percent of total capital payments. CHA suggests that CMS re-evaluate its calculation to ensure that the capital outlier percentage is correct.

In addition, CHA recommends that CMS consider adjusting the methodology used to determine the outlier threshold in order to more accurately reflect the true CCRs. Historically, the outlier threshold has been overstated, which results in large payment cuts to hospitals. It is estimated that CMS spent only 4.64 percent, or about $400 million less than what it set aside in FY2007, and only 4.8 percent or about $300 million less than what it set aside in FY2008. If CMS uses the CCR-inflation methodology, it will continue to generate an inappropriately high outlier threshold and continue to underpay hospitals.

Capital Inpatient PPS

In the FY 2008 final rule, CMS made two changes to the structure of payments under capital PPS. The 3.0 percent additional payment that has been provided to hospitals in large urban areas was eliminated (amounting to $600 million from FY2008 to FY 2012) and the IME adjustment to capital payments to teaching hospitals in being phased out over three years (amounting to an additional $1.3 billion over five years). These cuts are based upon the discretion of the administration with no Congressional direction.

CHA represents a health ministry which forms an important part of America's safety net institutions, and includes many Catholic hospitals serving a disproportionate share of the low-

income, uninsured, and underinsured in their communities every day. These capital cuts will impair the ability of these hospitals to continue investing in new technology, ongoing maintenance and improvement of hospitals' facilities and medical education. CHA strongly urges restoration of these capital payment cuts.

<u>Reporting of Hospital Quality Data for Annual Hospital Payment Update</u>

In the proposed rule, CMS outlines its vision for the future of the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program including retiring one measure, adding 43 measures for payment in FY 2010, and identifying 59 additional measures for inclusion in FY 2011. CHA is pleased that CMS continues to show a strong commitment to pay-for-reporting in the absence of the legal authority to begin value-based purchasing. However, we have reservations about the volume of the measures proposed and the increasing resources required to track and report them. We also question whether the proposed measures are truly mature enough for public reporting and tying to payment. Disease areas with no actual associated measures were among those CMS put forward for implementation in 2011. While we believe it is healthy to begin a national discussion well in advance of implementation, we suggest that CMS follow a more methodical framework to bring measures on line. We also suggest that CMS determine a process in which quality measures can be taken "off-line" when they are deemed to be universally implemented.

Proposed Quality Measures for FY 2010.

CHA supports the adoption of the Surgical Care Improvement Project (SCIP) Cardiovascular 2: (Surgery Patients on a Beta Blocker Prior to Arrival Who Received a Beta Blocker during the Per-operative Period) measure in the RHQDAPU for FY 2010. This measure has been endorsed by the National Quality Forum (NQF) and field tested. Thus, hospitals would have sufficient advance notice to implement evidence-based care guidelines.

While CHA does not support the adoption of the following measures in the RHQDAPU program at this time, we believe that CMS should track them for possible future inclusion. These measures include the proposed:

- Six venous thromboembolism (VTE) measures.

  While the VTE measures are NQF and Hospital Quality Alliance (HQA) endorsed and have clear guidelines on appropriate care, field testing was just completed and the final measure specifications will not be available until late 2008. Thus, the VTE measures are not ready for implementation by hospitals.

- Three readmission measures.

  CHA is also concerned with the problematic nature of these measures. For example, it is not unusual for patients discharged from one hospital to be readmitted to another facility. Clearly the second facility cannot be held accountable for the readmission, as it did not participate in care of the index admission. Yet, the decision to admit the patient to a second facility is clearly under the sole discretion of the attending physician with medical staff privileges at the respective facility. Therefore the first facility is in some respects being held accountable for the admission policies of the second.

It is also true that, despite the best efforts of the provider, patient non-compliance accounts for a portion of hospital readmissions. This risk is most likely not uniformly distributed among the population, but varies with educational and socioeconomic factors and with access to care which often varies with insurance status and ability to pay.

Until such time as these issues can be explored and accounted for more fully, CHA supports continued research in this area, and feels the public is not well served by the reporting of unadjusted or under adjusted readmission rates.

- Five stroke measures.

  We do not believe the measures are ready for implementation in FY 2009. These measures are not NQF or HQA endorsed. CMS should continue tracking these measures for subsequent adoption including any modifications based on testing.

- Nine measures from the Agency for Healthcare Research and Quality (AHRQ)

  Only 3 of the 9 proposed AHRQ measures have been endorsed by HQA. The concern with the AHRQ indicators is their specificity and sensitivity to concretely identify occurrences. We believe the remaining measures are not sufficiently through the consensus building process for CMS to implement these measures for FY 2010.

CHA does not support the inclusion of the following measures in the RHQDAPU program unless significant advancements are made in the restructuring of these measures and their specifications:

- Four nursing sensitive measures:

  While these measures were NQF endorsed, the nursing sensitive measures were not intended for public reporting. In addition, these measures are in the middle of field testing, the preliminary results of which suggest that significant changes to the measures and their specifications will be needed. These revised specifications may not be ready until 2009. Thus, we expect that the measures will need to return to the NQF for a second round of consideration.

- CMS is proposing the addition of 15 cardiac surgery measures for payment in 2010 based on data from the Society of Thoracic Surgeons (STS) Cardiac Surgery Clinical Data Registry:.

  CHA opposes the integration of quality measures based on registry data into the RHQDAPU program. In this regard, CHA opposes the inclusion of the proposed 15 cardiac surgery measures for payment in 2010 based on data from the STS Cardiac Surgery Clinical Data Registry.

  While we appreciate that CMS is looking for alternatives to reduce the reporting burden on providers, we do not believe this is the way to accomplish that goal. We are concerned that the proprietary nature of private registries could diminish the transparency of the program. Public reporting of quality measures is only meaningful if the measures used are reliably comparable across all reporting institutions, which requires that institutions follow identical

data collection protocols that are well specified. Consistent, identical data collection processes can only occur if the measure reporting and calculation mechanism is transparent and understood by all participants and by the public at large.

We are also concerned that adding data submissions through registries will place yet another data abstraction burden on hospitals, even if they are already participating in the required registries. Many of the proprietary registries require significant manual abstraction of data, which is expensive and can be prone to error.

We are concerned that the use of registries will not reduce the burden on hospitals for data collection and could actually increase it. Further, requiring participation in registries to comply with public reporting may unintentionally encourage the proliferation of registries, which will decrease rather than increase efficiency.

Possible New Quality Measures, Measure Sets, and Program Requirements for FY 2011 and Subsequent Years

CMS identifies 59 additional measures for possible inclusion in RHQDAPU in FY 2011 or later. The list includes measures pertaining to a range of areas such as complications of vascular surgery, healthcare associated infections, timeliness of emergency care, surgical care improvement, healthcare acquired conditions, hospital inpatient cancer care measures, "never events," and preventable hospital-acquired conditions.

CHA is concerned about CMS' approach for addressing additions to the RHQDAPU program in the future. We believe CMS should take a more purposeful, rationale, and calculated approach such as suggested above. CMS should also prioritize these measures according to their value in improving quality and reducing costs, their utility to beneficiaries, the level of burden imposed on providers and their readiness for implementation. The unmanageable list presented in this year's rule only served to unsettle providers who are already having trouble keeping up with all of the new requirements. The program should be slowly and steadily expanded rather than growing exponentially

Other Quality Reporting Issues:

- **Data from States and Other Sources.** CMS also inquires about the use of data from state data organizations, state hospital associations, federal entities such as AHRQ and/or other data warehouses. CHA is supportive of CMS accepting data from these and other sources that provide publicly available, transparent data as long as it does not cause additional data management burden on the hospitals.

- **Continuity Assessment Record and Evaluation (CARE).** In the rule, CMS suggests the possible use of the CARE tool to collect data in the future. The CARE tool is being tested as part of the Post Acute Care (PAC) Payment Reform Demonstration that just began and is not yet fully operational. Given that the measure set was never validated and the report to Congress is not due in 2011, we believe it is premature to discuss the possible use of this tool. In addition, CHA is hesitant to support the integration of a patient assessment instrument into the hospital setting at this time given the experience of post-acute providers

with such tools. At this time, CMS should continue to focus on developing and integrating quality measures based on evidenced-based care that have been shown to improve healthcare quality into the program rather than adding forms to the process. Moreover, CMS should not consider the use of this tool until it is indeed interoperable with providers' systems so that data can be directly downloaded.

- **Small Number of Cases.** CHA supports the proposal to eliminate certain data reporting requirements for hospitals that treat a small number of patients covered by data submission requirements.

- **Updating of Existing Measures.** CHA supports the proposal to update two existing measures that have had specifications updated by the NQF for FY 2010: the acute myocardial infarction (AMI) measure regarding the timing of Percutaneous Coronary Intervention (PCI) and the pneumonia measure pertaining to initial antibiotic treatment.

- **Chart Validation Requirements.** CHA supports the proposed move to select more charts for validation purposes from randomly selected (but fewer) hospitals to better ensure the accuracy of the validation process as well as supports proposed revision to select the sample based on clinical topics.

Proposed Changes Relating to Applicability of Emergency Medical Treatment and Labor Act (EMTALA) Requirements to Hospital Inpatients.

Proposed Changes Relating to Applicability of EMTALA Requirements to Hospital Inpatients.

CHA is concerned about the proposal to clarify the EMTALA regulations to state that when an individual covered by EMTALA is admitted as an inpatient while unstable, another receiving hospital with specialized capabilities has an obligation under EMTALA to accept the individual, assuming that the transfer of the individual is an appropriate transfer and the receiving hospital with specialized capabilities has the capacity to treat the patient. As CMS points out, this policy may indeed facilitate patient dumping to hospitals with specialized capabilities. But we are also sensitive to the existence of patients who would not otherwise not be able to get the specialized care they need. CMS would need to set up an extensive system to track and ensure that inappropriate transfers do not result.

Proposed Changes to the EMTALA Physician On-Call Requirements.

CHA supports the proposal to allow hospitals to satisfy the requirement that they maintain on-call lists through participation in "community call plans." Each hospital participating in the plan must have written policies and procedures in place to respond to situations in which the on-call physician is unable to respond due to situations beyond his or her control. We believe this proposed policy is particularly important in rural and other areas where physicians are in short supply. We are concerned, however, about the proposed specificity of the requirement and urge CMS to provide flexibility for hospitals to best and uniquely respond to this option.

Application of Incentives to Reduce Avoidable Readmissions to Hospitals

CMS is considering three options for developing incentives to reduce avoidable readmissions:

- Direct adjustment to DRG payments;
- Performance-based payment adjustment; and
- Public reporting.

CMS does not currently have the authority to implement the first two possibilities. However, we support the consideration of readmission measures into a full-scale pay-for-performance program similar to the HQID project once authorized by Congress and implemented.

We do not, however, support the direct adjustment of DRGs at this time. CMS should not penalize hospitals but rather provide incentives for hospitals to improve care and reduce costs.

As noted earlier, we are also concerned about the following:

- Patients discharged from one hospital are frequently readmitted to another facility.
- The decision to admit the patient to the hospital from which the patient was initially discharged or to a second facility is clearly under the sole discretion of the attending physician with medical staff privileges at the respective facilities.
- Despite the best efforts of the provider, patient non-compliance accounts for a portion of hospital readmissions.
- Just measuring readmissions alone may encourage hospitals to keep patients longer, whether that is appropriate or not and increases costs.

Until such time as these issues can be explored and accounted for more fully, CHA supports continued research in this area, and feels the public is not well served by the reporting of unadjusted or under adjusted readmission rates.

Disclosure Required of Certain Hospitals and Critical Access Hospitals (CAHs) Regarding Physician Ownership.

CHA supports the proposal to include in the required disclosure list of hospital ownership any immediate family member of a physician who holds an ownership or investment interest in the hospital.

CHA also supports the proposal to require that a hospital must furnish to a patient the list of owners and investors who are physicians (or immediate family members of physicians) at the time the list is requested by or on behalf of the patient.

And CHA supports, with qualification, the proposal to require a hospital to require all physicians who are members of the hospital medical staff to agree, as a condition of continued medical staff membership or admitting privileges, to disclose in writing to all patients who they refer to the hospital any ownership or investment interest in the hospital held by themselves or by an immediate family member. CHA, however, is concerned with the proposed penalty that CMS could terminate the Medicare provider agreement if the hospital fails to comply with this provision. It is important that such a penalty provision clearly distinguishes between a hospital making such a disclosure a condition of medical staff membership and the compliance of the respective physician.

Physician Self-Referral Provisions

Stand in the Shoes Provision.

The physician self-referral law prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies and prohibits the entity from filing claims with Medicare for those referred services.

In September 2007 CMS published a physician-self referral final rule ("Phase III") which was designed to address situations in which the respective physician financial arrangements posed no risk of program or patient abuse. CMS, however, in response to concerns raised by academic medical centers (AMCs) and integrated tax-exempt health care delivery systems ("integrated delivery systems") regarding the rule's impact on compensation arrangements involving "mission support payments" and "similar payments" (collectively referred to as "support payments"), issued a final rule in November 2007, which delayed the implementation of certain sections of the September rule for 12 months. The delay only applied to an AMC with respect to a compensation arrangement between a faculty practice plan and another component of the same AMC and an integrated delivery system involving a compensation arrangement between an affiliated DHS entity and an affiliated physician practice in the same integrated system.

In response, CMS is proposing two alternatives ways to address the concerns of the AMCs and integrated delivery systems.

The first proposal would, among other requirements, provide that that a physician would be deemed not to stand in the shoes of his or physician organization if the compensation arrangement between the physician organization and the physicians satisfies one of three exceptions. The exceptions include the exception for bona fide employment relationships, the exception for personal service arrangements and the exception for fair market value compensation.

CHA is opposed to this proposal primarily because there is no bright line. Not only would the physician need to meet one of the three exceptions, his or her financial arrangement would have to pass an evaluation of any indirect compensation arrangements. And, in addition to these tests, CMS notes that there would be several other "tests" that would be applied to the situation. Together, the exemptions, evaluations and tests would appear to the typical physician as bureaucratically confusing.

The second CMS proposal would simply leave the Phase III "stand in the shoes" provisions as promulgated and would instead create a new exception for nonabusive arrangements that warrant protection not available under existing exceptions. While, as CMS correctly noted, there are a number of definitional issues along with certain documentation requirements and related assurances, CHA feels that this may hold the most promise for creating a new exception for compensation arrangements between DHS entities and physician organizations and physicians for "mission support" payments.

Period of Disallowance.

In response to an earlier Phase II physician self-referral final rule, questions were raised about what the time period would be during which the physician could not refer patients for designated health services (DHS) to an entity and for which the entity could not bill Medicare where a financial relationship between a referring physician and an entity failed to satisfy the

requirements of an exception to the general prohibition on self-referral. In the CY 2008 physician fee schedule proposed rule CMS solicited comments with respect to several related issues. There were few public comments.

In this proposed rule CMS makes several proposals in response to the above question.

CHA is concerned about the proposal that, where the reason(s) a financial relationship does not meet any applicable exception is not related to compensation, the period of disallowance would begin on the date of the arrangement first was out of compliance and end no later than the date the arrangement was brought into compliance. Our concern relates to the seemly draconian requirement to return all the reimbursement for a relatively minor infraction such as a missing signature during the proposed period of disallowance.

We urge CMS not to impose a period of disallowance for such an infraction or to consider adding an appeal process to address circumstances in which disallowance may not be in the best interests of patient care and quality. The classic example of the unintended impact of this rule is the rural hospital with one cardiac surgeon who is badly injured in a car crash and the hospital scrambles to locate a an appropriately qualified physician to ensure coverage of this vital service to the community, and where getting the new physician in place as soon as possible is more important that getting the contract signed by all parties, after each side has reviewed it with their respective counsel. If the period of disallowance is allowed to stand in such instances, the hospital, to avoid both non-reimbursement and a new fraud and abuse violation, would not be able to permit the replacement physician to start until the signed papers are on file (for fear of providing free/non-billable care to federal health care program beneficiaries and invoking a new fraud and abuse violation). This could result in having to transfer patients needing such services elsewhere until such time as the signed, sealed document is in hand.

CHA is also concerned about the proposal that, where the reason a financial relationship does not meet any applicable exception is related to the payment or receipt of excess compensation the period of disallowance would begin on the date the arrangement first was out of compliance and end no later than the date the excess compensation was returned by the party receiving it to the party that provided it.

There are several reasons for our objections:

- The physician may not have been aware that he or she was in violation of one or more physician self-referral prohibitions. For instance, the physician may not have known that his or her compensation arrangement was greater than the fair market value or exceeded the limits for such services. The physician may have assumed that the entity, which contracted with him or her, knew the rules and had structured the relationship accordingly to avoid violating any restrictions. Further compounding this situation is that the typical physician, in many cases, simply does not know where to find the appropriate information that would clearly show the relevant values and/or limits.

- In turn, the entity contracting with the respective physician may not have known the appropriate value or limits associated with the respective physician services. Again, the entity, which could be a rural hospital, simply may not have had have the resources or experience to ascertain whether the arrangement violated any appropriate prohibitions.

- The proposed period of disallowance would apply to all compensation related violations regardless of whether the violation is the first such instance for a given entity or one that reflects a pattern of violations for an entity.

As an alternative, CHA urges CMS to consider a policy that would apply to the first compensation-related violation a lighter period of disallowance than where the violation is not the first for either the physician or the entity. For instance, for a first compensation-related violation of the physician self-referral prohibition limit the period of disallowance from the date the arrangement was first out of compliance and end no later than the earliest of (a) when the excess compensation was returned or (b) six-months assuming the respective physician legally commits to a reasonable repayment method. Such a legally binding repayment method would require CMS to provide guidance on when interest is required and what rate is appropriate. Obviously, if the physician subsequently fails to abide by the pledge, the period of disallowance would be re-installed until such time as the excess compensation is fully repaid.

Disclosure of Financial Relationships Report (DFRR).

CHA is deeply concerned about the significant time and use of staff resources necessary to complete the proposed 24-page information collection instrument designed to capture information concerning hospital/physician financial. While CMS estimates that it will take, on average, about 31 hours for a hospital to complete this survey, comments from our members indicate it will take many times this estimate to adequately complete the survey. The estimate grows exponentially with the size and mission of the respective hospital. Smaller hospitals and those without the resources to have already converted records to an electronic format will face an even greater burden in identifying all of the relevant physician arrangements; identifying and gathering all of the pertinent written agreements and supporting documentation; calculating non-monetary compensation; and reviewing and preparing the materials for final certification by the hospital.

In closing, thank you for the opportunity to share these comments in regard to the proposed FY 2009 IPPS rule. We look forward to working with you on these and other issues that continue to challenge and make stronger the country's hospitals.

Sincerely,

Michael Rodgers
Senior Vice President, Public Policy & Advocacy