

**Recommendations of Members of the
Catholic Health Association of the United States
to the
Secretary's Advisory Committee on Regulatory Reform**

**Submitted to Honorable Tommy G. Thompson, Secretary
U.S. Department of Health and Human Services**

**In response to his
Regulatory Reform Initiative**

June 2002

Preface

The enclosed compilation is a gathering of the various perspectives submitted by members of the Catholic Health Association of the United States to the US Department of Health and Human Service in response to Secretary Tommy Thompson's 2001 Regulatory Reform Initiative.

The compilation is organized to correspond to the issues areas designated by HHS. It includes recommendations submitted directly to HHS from CHA members, recommendations presented during field hearings held by the Secretary's Advisory Committee on Regulatory Reform, and recommendations submitted independently to CHA. In assembling this compilation for submission to Secretary Thompson and for the information of the CHA membership, CHA sought to perform a clearinghouse role only. The membership as a whole has not endorsed all or part of these recommendations. It is also important to note that other CHA members have responded to Secretary Thompson's initiative by commenting through other membership organizations or coalitions.

The Regulatory Reform initiative presents a unique opportunity to influence an area of concern to all who strive to deliver the best possible health care with compassion and efficiency. We are grateful for Secretary Thompson's recognition of how much over-regulation impedes our ability to do this.

The names of individual contributors and their contact information are included in the Appendix to this compilation.

We particularly want to thank those who served as reviewers for this project, including: Nancy Baerwaldt and her colleagues from Trinity Health; Sr. Marjorie Bosse, RSM and Don Koenig from Catholic Healthcare Partners; Steve Brennan from Providence Health System; Carmela Brown and her colleagues from Catholic Health Initiatives; Joeann Karibo and her colleagues from Bon Secours Health System; and Shelly Schlenker and her colleagues from Catholic Health Care West. Their assistance has been invaluable.

**Recommendations of Members of the
Catholic Health Association of the United States
to the
Secretary’s Advisory Committee on Regulatory Reform**

**Table of contents
Recommendations by HHS Issue Area**

	<u>Page</u>
<u>Data and Information Requirements</u>	1
Medicare Cost Reports	
Nursing Home Admission Forms	
OASIS	
<u>Regulatory Flexibility and Process</u>	9
Conditions of Participation	
Homebound	
Presentation of Regulations	
<u>Communications and Oversight</u>	10
Certification Process	
Seclusion and Restraint Regulations	
EMTALA	
Stark Law	
<u>Coordination</u>	22
New Technology Coverage (FDA/CMS)	
State/Federal	
Timeliness of Regulatory Promulgations	
<u>Other Provider-Specific Issues</u>	25
Nursing Facilities	
Rural Health	
Other Providers Issues	
<u>Other</u>	28
Coverage and Reimbursement Issues	
Codes and Coding Policies	
ERISA and Nurse Shortages	
HIPAA	
<u>Appendix</u>	38
CHA-Member Contributors and Contact Information	

**Recommendations of Members of the
Catholic Health Association of the United States
to the
Secretary's Advisory Committee on Regulatory Reform**

June 2002

Data and Information Requirements

Medicare Cost Reports

1. Improve and/or simplify Cost Reports: The Medicare Cost Report, used to gather data for financial accounting, quality measurement, utilization data and other purposes, has become an unwieldy, time- and resource-consuming document to prepare and submit. Moreover, with the move to prospective payment for the major service lines for Medicare beneficiaries, its value as a financial tool for the Medicare program is lessened.

Recommendation: CMS should redesign and/or streamline the current cost report structure to make it easier to prepare, more user friendly, and more useful and meaningful for the government, the preparers, and the users. The "cost" reports should be redesigned in such a way that it is relatively easy to prepare and tell what sections are done to meet certain defined objectives such as: to provide bases for payment reconciliations and settlements, for setting rates, for setting general indices, etc.

(Submitted by Steve Brennan, System Director, Advocacy & Public Policy, Providence Health System)

2. Streamline the Medicare Cost Report. The Secretary should evaluate and overhaul the Medicare cost report, reducing its size and complexity to reflect Medicare payments based on prospectively set rates, not cost-based reimbursement, and modify or eliminate arcane Medicare specific cost accounting principles.

(Submitted by Sr. Marjorie Bosse, Vice President, Catholic Healthcare Partners, Cincinnati, OH)

3. Outstanding Cost Reports (42 CFR 405.1803(a) and 42 CFR 405.1835(c)): Under Section 1878(a)(1) of the Social Security Act, a provider seeking reimbursement for covered health services from respondent Secretary of Health and Human Services submits a yearly cost report to a fiscal intermediary (generally a private insurance company), which issues a Notice of Program Reimbursement (NPR) determining the provider's reimbursement for the year. The Act gives a dissatisfied provider 180 days to appeal a reimbursement determination to the Provider Reimbursement Review Board, whose decision is subject to judicial review in federal district court.

However, Fiscal Intermediaries in many cases do not issue an NPR in a timely fashion, particularly when there is a question about reimbursement. This has resulted in outstanding cost reports that can be several years old – meaning providers do not know for sure whether they will be paid for services rendered.

Recommendation: CMS should require the Fiscal Intermediaries to issue NPRs no later than 18 months after the cost report was filed. Additionally, CMS should define an "open" cost report as a cost report for which the intermediary has not issued a NPR.

(Submitted by Steve Brennan, System Director, Advocacy & Public Policy, Providence Health System)

Medicare Cost Reports con't.

The following four recommendations on cost reports were submitted by Keith E. Braganza, Director of Budget, Bon Secours Health System, Inc., Maryland.

1. Medicare Cost Report

- A. Issue -- Data required to be filed in Cost Report
- B. Situation -- Annual report required to be filed.
- C. Background -- Cost reports have not been changed (reduced) to incorporate the move to prospective payment for inpatient and outpatient hospital care.
- D. Intent of Current Law or Rule -- No regulations need to be changed. Only the Provider Reimbursement Manual will need revision. The intent of the Manual provisions is to effect extremely accurate cost finding.
- E. Proposed Reform -- Reduce the contents of the cost report. See details below.

Worksheet S-3

- Add a line for qualified but unpaid Medicaid days used to compute the DSH percentage. This would assist in calculation of the DSH percentage.

Worksheet A.

- The number of cost centers listed should be reduced, particularly the overhead (non-revenue producing) cost centers.
- Eliminate old capital and new capital cost centers. Have a single line for capital.
- Eliminate the option for component allocation of administrative and general costs.
- Combine employee benefits, nursing administration, and medical records with administrative expenses.
- Combine operation of plant, housekeeping and laundry and linen, dietary and cafeteria into a single cost center.
- Eliminate cost centers for central services and supply, and pharmacy. Central services and supply should be classified into Medical Supplies (Charged to Patients); and pharmacy should be classified as Drugs (Charged to Patients).
- Combine all special care units (ICU, CCU, NICU, etc.) into a single cost center.
- Operating room, anesthesiology and recovery room should be combined.
- Blood should be combined with laboratory.
- Electrocardiology and electroencephalography should be combined.
- Combine all therapy cost centers for home health.
- All non-reimbursable cost centers should be combined into a single cost center.

Worksheet A-7 -- This worksheet should be eliminated.

Worksheet A-8 -- Eliminate rows on this schedule consistent with the changes on Worksheet A.

Worksheet A-8-1 and A-8-2 – Eliminate.

Worksheets B and B-1

These should be consistent with changes on Worksheet A.

Eliminate stepdown allocation. Have direct allocation to revenue-producing cost centers.

Worksheet B II and III – Combine these worksheets.

Worksheet C, Part I

Have only one RCC column for TEFRA and Other. Eliminate column for PPS inpatient ratio.

Worksheet D series – These can be combined

Worksheet D, Part V – Eliminate.

Worksheet D-1, Part I -- Eliminate calculation of private room differential.

Worksheet D-1, Part II -- Modify so that the 15% capital reduction is displayed.

Worksheet E, Part B

- Eliminate rows that pertain to lower of cost or charges calculation.
- Include outpatient on this worksheet.

Worksheets E, Parts C, D and E – These can be eliminated.

Worksheet E-3 – Eliminate rows used for lower of cost or charges calculation.

Worksheets G and L – Eliminate

Worksheet H series -- Given the move to PPS for home health, these can be abbreviated.

F. Immediate Reform -- Given that no regulatory changes are necessary, this can be implemented immediately.

G. Who would be Affected? -- Providers, intermediaries, consultants (who prepare cost reports).

2. Provider Reimbursement Manual

A. Issue -- Consistent with the recommendation above, certain sections of the Provider Reimbursement Manual will require revision. These pertain to statistical allocation of overhead costs.

B. Situation -- On the cost report, overhead costs are allocated based on statistics (e.g., timesheets, which have to be maintained throughout the year). If the cost centers are to be

reduced, the need for exactitude in allocation will also be reduced. Under prospective payment, exact costs by department are no longer as important since they will not affect reimbursement/payment at all.

- C. Background -- The sole purpose of statistical record keeping was to effect accurate allocation of costs to revenue producing centers. Under prospective payment, that is no longer necessary.
- D. Intent of Current Law or Rule -- To calculate costs accurately
- E. Proposed Reform -- Medicare Manual Provisions that Should be Eliminated or Revised:
 - Eliminate the requirement for timesheets for statistical allocation.
 - Timekeeping requirements for hospital-based physicians should be reduced.
- F. Immediate Reform -- This can be implemented immediately, since no regulations need to be changed.
- G. Who would be Affected? -- Providers and intermediaries.

3. Accounting Principles

- A. Issue -- Consistency of accounting between Medicare and GAAP. Specifically, accounting for capital costs (depreciation and losses on defeasance).
- B. Situation -- Depreciation expense for Medicare often differs from that under GAAP. As a result, providers have to utilize resources to maintain two separate sets of fixed asset records. Losses on defeasance of debt are recognized immediately under GAAP, but for Medicare the loss has to be amortized over the term of the refunding debt. Since most debt is for a long term, the detailed records of amortization (for Medicare purposes only) have to be maintained.
- C. Background -- This was necessary under cost reimbursement, particularly when hospitals were sold at a gain or loss and goodwill was accounted for under GAAP. However, payment for losses on sale were eliminated by legislation in December 1997. Since cost reimbursement has been almost completely eliminated, GAAP treatment of losses on defeasance of debt does not affect payments to hospitals.
- D. Intent of Current Law or Rule -- To accurately calculate costs – specifically, the cost of depreciation and losses on defeasance of debt.
- E. Proposed Reform -- Medicare Manual Provisions that Should be Eliminated or Revised:

DEPRECIATION -- Eliminate distinctions between Medicare depreciation and depreciation per financial statements. Eliminate the Medicare requirement on asset lives. Use generally accepted accounting principles.

LOSSES ON DEFEASANCE OF DEBT -- Eliminate rules on gains and losses on defeasance of debt. Treat these consistent with GAAP.

- F. Immediate Reform -- These can be effected immediately, since no regulations will need to be changed.
- G. Who would be Affected? -- Providers and intermediaries.

4. Home Office Cost Reports

- A. Issue -- Home Office Cost Reports are unnecessarily detailed, especially given the prevalence of prospective payment.

- B. Situation -- Home Office Cost Reports allocate the costs of a corporate office to all units in a chain (system), even if for many of those units, cost reimbursement does not exist at all. Also, the intermediary audits of Home Offices are usually done separately from the audits of providers. As a result, cost reports that were settled based on unaudited home office costs have to be reopened. For hospitals under prospective payment, there is no difference at all in payment. It is merely a paper exercise.
- C. Background -- Under cost reimbursement, it was necessary to get the costs of a corporate office allocated to the providers so that the complete costs of providers could be identified.
- D. Intent of Current Law or Rule -- The intent of the rule was to effect accurate cost finding.
- E. Proposed Reform -- Medicare Manual Provisions that Should be Eliminated or Revised: The Home Office Cost Report should have allocations to only those entities that are cost reimbursed. For example, hospitals with psychiatric units, children's hospitals, etc.
- F. Immediate Reform -- This can be implemented immediately. No regulations need to be changed.
- G. Who would be Affected? -- Corporate offices, hospitals and intermediaries.

Nursing Home Admission Forms

Nursing Home Admissions (excerpt from Eileen Mulaney testimony at January 7 Advisory Commission Hearing)

I thought one way to experience another health care setting is to experience it. I've brought papers with me and put them on your tables. They are a contract if you were admitting to a nursing home. I thought if we could go through them together, you might get the sense of how it feels if you're admitting to a nursing home. Let's say you had a hospital stay. Perhaps you've replaced a hip or a knee, and now it's time for you to come to a subacute unit. Or let's say, like our friend here, you're sitting here and you just got a call from your spouse who said, come home, your father is ready to go to the nursing home. His hip is ready to go to the subacute unit. And it's your chance to admit into a health care setting where we give subacute care.

Everyone that does come in, we have to sit down with them and sign a contract, a normal contract between our party who are going to provide services and you who are going to pay for these services or have your insurance company pay for these services. So first we say, this is a contract. And we write it in very big, bold print because we want anyone who comes in to understand what they're signing and to be comfortable with it. We spend considerable time training people consistently about the regulations, about the factors in the contract. We have our nicest people doing this job, and it still is quite difficult.

So if you would come with me then, we have a contract. I have some paperwork here that our financial office would want to sit down with you and discuss. And then I do have a package here to show our UB-92 billing and some MDSs which are attached, which is the clinical review of the resident, which has to match the billing in order for us to receive payment.

There's a Medicare determination act. If we find someone no longer needing Medicare, we have an obligation to give them this piece of paper so they can appeal our decision. Then the last package is a Medicaid application, which every state would have. Oftentimes in our position as a provider, we have to help a person apply for Medicaid assistance because they turn into perhaps what we would

call a long-term care resident. They cannot go home. Their circumstances are such that they're going to need nursing home care for the rest of their life.

So if we were to admit, we'd get your name and we'd also ask you for the name of a responsible party. Most of the residents who admit to Carroll Manor really want a son or a daughter and they may even have guardian at this point taking care of them. So we'd need to get that name at this time.

We talk about the payment source. Let's say in this case it's going to be Medicare. We would advise them of what's in their per diem and what is not, any other charges. The biggest one we have is the hair/beauty salon. It's not a big item. We talk about the payment of the bill, how that would occur, talk to them about how they could select a doctor, what doctor they would like to have. We talk to them about their right to bring in a private duty nurse if they felt they needed that or wanted that.

We have to inform them that they have a right to have their bed held if they have to go back to the hospital. They can pay for that privately or, if they're in Medicaid assistance, they do get 18 days that are already paid for by the state government. We have to alert them to the fact that if they have any complaints, they can go to the state or the ombudsman and give them their number and name. We talk to them about their right to make a decision, about end-of-life decision making. We talk to them about our right to transfer or discharge them, under what circumstances we would do that. Of course, it would only be if we could no longer help them in the improvement of their own care or if we closed our facility or if they became a danger to themselves or others. We talk about the right to end this contract, our ability and our limitations on our liability, as well as changes in the law, what effect they might have.

There are a number of exhibits that we are required to advise somebody coming into a nursing home about. They are attached. They include the obligations and responsibilities of the representative, and we do have to walk that person, be it a son or a daughter or a guardian, through all the obligations that they have and that they're signing and what their signature does mean under the law with this contract. We also talk about the schedule of charges, the Medicare and Medicaid, what do they cover. We do find that it's necessary to spend a considerable amount of time educating people on the Medicare program, the Medicaid program, third party insurance.

We offer them a physician's services and talk about the physician rotation service at Carroll Manor. We do have to give them their rights and responsibilities as outlined in OBRA. There is a form here for the bed-hold policy which they can sign in advance. We also have to educate them about their legal right to decide about future medical treatment and ask them if they do have a durable power of attorney. If they have those documents, of course, we try to get them and pull them in at this time. We ask them any information about their funding, if they'd like us to collect all that money and have it sent right to Carroll Manor, if we should take care of their funds for them or if they want, again, a family member to take care of them.

Then we have to inform them about the fact that their MDS data -- and that's the minimum data set -- all the assessment data that we are doing on any resident in the facility is transmitted over electronic wire or electronic forces to now CMS and to the state.

So that is the contract experience. Now, if there are questions raised during that, we do also at this point try to tell them that they will have CMS and the Centers for Disease Control and also our DelMarVa, which is our local peer review -- we're moving with them to a standing order for the flu and the pneumococcal vaccine. So we have put an additional paper in our contract advising them that we are moving to a standing order and that their giving us consent will be consent for the length of their stay at the nursing home. We also have a copy of our valuables policy here so they can understand how we secure their valuables. We certainly encourage people not to bring them in if at all possible.

If you'll go through the contract, there are a number of cases where we cause them to sign so that we have evidence and they have evidence that they have been informed of these rights. But it's about an hour's process to take a person -- and this is a person who is clear and able -- through this contract. If you come in and you're not feeling well, your position or your disposition is I don't want to do that or I can't do it now or I really don't want to handle that or my son will handle that or I'll do it later. You see a lot of people wanting to postpone this action.

Once we do have the admission contract signed, the person may have to go in and meet with the folks in the financial office in order to clear up the benefit and the flow of funds and how that will all occur. I've got a regular checklist here that we go through in our financial office, so you'll see all the paperwork that we have to make sure is in place when somebody is coming into a nursing home. And they are things all the way from power of attorney, as we've discussed, documented burial arrangements, assignment of benefits to Carroll Manor, if they want to use our resident fund account, and all information of course on their insurance. And there are copies of the bed-hold agreement in this document as well.

The next package is a UB-92, and these are the billing forms that we send to the federal government. On the stay that we've got here as an example, we have a 100-day stay of a resident. We do file MDSs, and on the subacute unit we file a 5-day, followed by a 14-day, followed by a 30-day, followed by a 60-day, and followed by a 90-day. And that sequence would afford a 100-day stay, which is the benefit under Medicare. These are filed according to the month you're in rather than to the stay. So it is difficult for the billing office to go through the clinical documents and to make sure that they put the number of days in the month according to the RUG category on the billing form correctly. For example, in this package I've given you, the billing for December, we have 13 days of the 5-day Medicare statement, and on the next month, which is January, we have 1 day remaining for the 5-day, and then 16 days for the 14-day statement, and 14 days for the 30-day statement. The next month we have 16 days for the remaining 30 days, 12 days for the next 60-days, and then the next month we have 18 days for the remaining, and then for the final MDS, we have 10 days, making the 100-day stay. So this is a very difficult operation, and the penalties to a provider for doing this incorrectly are quite severe. I appreciated your remark about a Ph.D. I think that's enough, and I'll be here for questions. Thank you.

(Submitted by Eileen Mulaney, Carol Manor Nursing Home, Providence Hospital, Washington, DC)

OASIS

1. OASIS -- Barriers to recruiting and retraining nurses. Outcome and Assessment Information Set (OASIS) has been a requirement of Medicare Certified Home Care Agencies since October 1998. CMS requires that each patient receive from the home health agency a patient specific, comprehensive assessment that identifies the patient's need for home care and that meets the patient's medical, nursing, rehabilitative, social, and discharge planning needs. The Conditions of Participation sections citing this regulation are 484.11, 484.20 and 484.55. The OASIS tool itself consists of 96 questions that are interspersed throughout the comprehensive assessment and is used when evaluating all adult and non-maternity patients, regardless of payer. The OASIS questions are then transmitted to the State, within specific date sensitive guidelines.

The increased paperwork and ongoing regulatory education needed for the implementation of OASIS has made recruiting and retaining of nurses very difficult. OASIS is often cited as the

number one reason why nurses are leaving home health care. As a result, OASIS has exacerbated the already scarce supply of available and qualified nurses nationwide. Home health nurses typically must spend more time complying with federal paperwork requirements than providing hands-on care during one 60-day episode of patient care. In addition the cost of OASIS far exceeds the reimbursement since home health agencies are not compensated for the cost of professional staff time or for the technology that has been necessary for OASIS and prospective payment system (PPS) implementation.

(submitted by Carmela Brown, Government Relations, Mercy Medical Center, Des Moines, IA)

2. OASIS Assessment: This requirement's primary objective is to determine payment for Medicare beneficiaries under the Home Health Prospective Payment system. However, it is applied across the board to all home health patients regardless of payer source. The OASIS assessment is very lengthy and covers much more than is necessary to establish payment. The requirement should be applied only to Medicare patients. Additionally, questions that do not contribute to the calculation of payment and that are not utilized in outcome assessments should be deleted.

(Submitted by Nancy A. Baerwaldt, Vice President, Advocacy, Trinity Health)

Regulatory Flexibility and Process

Conditions of Participation

Shield for Quality-Improvement Activities Using Peer Review Materials. Many health care systems are implementing quality improvement initiatives that involve a conscientious assessment of materials acquired through the peer review process. To promote this desirable undertaking there should be an explicit federal mandate that shields from discovery peer review materials used for quality improvement initiatives.

Regulatory language akin to the following will accomplish the desired objective: "Data collected for a **quality improvement** or peer review function are confidential, shall not be public records, and shall not be available for court subpoena."

(Submitted by Nancy A. Baerwaldt, Vice President, Advocacy, Trinity Health)

Homebound

Homebound Status Requirement. As a geriatrician I find that the home bound status requirement restricting home nursing care to Geriatrics patients is a serious impediment to providing preventive care to frail elderly who would otherwise have more frequent exacerbation of chronic illnesses. Needless to say that there is an economic consequence as well in terms of utilization of more expensive services such as emergency rooms and hospitalizations. Home health agencies can identify a subset of elderly patients who would benefit from a waiver of the home bound status. Such screenings already exist in some states where there are waiver programs for Medicaid patients. It is also important to allow Medicare the flexibility to negotiate care for individual patients who are typically much more expensive to care for without home health care. A physician calling local Medicare assessors should have a chance to influence the care and services provided to their patients on a case by case basis. All the assessor needs to consider is the medical history, history of ER visits and hospitalizations and make a judgment based on case sensitive cost analysis.

(Submitted by Jabbar Fazeli, MD, Sisters of Charity Health System, ME)

Presentation of Regulations

Single Reference Source Needed. Approvals for new technology and pass-throughs are distributed through a variety of regulatory notices (e.g., CFR, Medicare Bulletins, Program Memoranda.) However, there is no one resource location for providers to obtain a single "master list" of approved technology and pass-throughs that reflects the real-time additions, revisions, and deletions made thus far. Providers must, on their own, piece together all the individual notices in order to obtain the complete snap-shot of changes. Providers are spending more time tracking down the changes than understanding and ensuring that changes are implemented.

Recommendation: A single source that reflects the most comprehensive daily list of covered supplies, the current coding, and status of the supply item is needed.

(submitted by Donald E. Koenig, Vice President, Corporate Responsibility, Catholic Healthcare Partners; Cincinnati, OH)

Communications and Oversight

Certification Process

Certification (excerpt from Margaret Barron testimony at January 7 Advisory Commission Hearing)

Thank you very much for this opportunity. CLIA is the Clinical Laboratory Improvement Act, and this has been around for a number of years. Like many other things, it had good intentions, to make sure that people know how to do the tests that they're doing and interpret them. It's a patient care issue. Well, it's gone a little bit too far, like many other things. I apologize for the nature of my audio-visual aids. I didn't realize I was going to be right after lunch, but they make a point. In front of you, you have a little card that most of you have had experience with in your doctors' offices, and it's a card to test for fecal occult blood. This is a straightforward test. The average medical student learns it the first day of junior year, the first day on the clinical wards. The average nursing student learns it, again, the first day in clinical medicine.

The test is classified as moderately complex. I have to certify that my physicians and nurses know how to do this. Now, the certification process -- first I have to give them a color-blindness test, and you have the 12 questions there, and I have to flip through this book. I mean, if they don't know they're color-blind on the first day of medical school, we've got problems. After I do the color-blindness test, which takes about 20 minutes, the last panel I really like. You have to trace with your finger the path through the color points here. So after I've done the color-blindness test, then I have to give them the 15-question true and false test about the fecal occult blood test.

Now, all of this takes me at least an hour to do a test that's this simple. The sample is on one side, open the card, put on the drop, drop, drop, and I wait the specified three to five minutes, and I read it within 20 seconds. That's the test. I'm supposed to do that four times a year.

The next test is almost as simple, and you've all seen this in your doctor's office. It's a urine dipstick, classified as moderately complex. The nurses dip the stick. There's a little jar. Again, we have to do the color-blindness test first. They hold the stick up and they read it against the jar, and you have to wait the required number of seconds, which is written right here on the jar, 60 seconds for most of the tests. We're supposed to do that four times a year. That is for 107 nursing employees and approximately 30 doctors. They're on the clock for this, so they're being paid, my time, the lab's time.

The glucometer test is even more simple. That's the one where you stick the finger, put it on the stick, and put it in the machine. For that one you don't even have to be color-blind to screw that one up. It's real simple. That one we have to test monthly for. It used to be quarterly, but now they have to do the test once a month. That's just a simple example.

When the commission came recently to do the certification process, they asked me to see my physicians' Gwyet competencies, and we had them. But I said to the reviewer, wouldn't you rather see the competencies to see if they know how to intubate a patient, put in a chest tube, open the laceration the correct way? "No, these are the only ones I have to ask you for. "Now, this should be part of credentialing. I should be able to credential someone for this, the same way we credential them to read an electrocardiogram. It doesn't need to be done once a year. If the test changes and the

lab sends out a memorandum, then fine, I need to check and teach everybody again. *But that's an example of regulatory burden that takes a lot of time and a lot of money to keep up with.*

(Submitted by Dr. Margaret Barron, MD, Providence Hospital, Washington, DC)

Seclusion and Restraint Regulations

Restraint and Seclusion (42 CFR 482.13(e) and (f)): The Patients' Rights Section of the Medicare Conditions of Participation includes a provision that requires acute care facilities and behavioral health facilities to provide face-to-face evaluation of patients who are restrained or secluded for behavioral management by a physician or licensed independent practitioner (LIP) within one-hour of the initiation of restraint or seclusion.

We support the federal government's goal to limit the use of restraints and seclusion in all health care settings. The health and safety of our patients are paramount, and even one tragic death or serious injury resulting from the use of restraint and seclusion is unacceptable. Restraint and seclusion should only be used when less restrictive measures are not feasible. However, when used properly, restraint and seclusion are lifesaving and injury-sparing interventions.

The requirement of a face-to-face evaluation by a physician or LIP within one hour, along with a re-evaluation after four hours, is medically unsupportable and places an undue staffing burden on inpatient psychiatric units, many of which are teetering on service reductions or closure due to poor reimbursement. The net result could be reduced access to patients in serious need of psychiatric and/or medical treatment.

Recommendations: We believe that the following regulatory changes would both maintain the intent of the underlying statute (Section 1861 of the Social Security Act) and the corresponding regulation by ensuring the safety of Medicare beneficiaries under specific circumstances in a manner that is consistent with best medical practice. They are: 1) Eliminate the requirement of a face-to-face evaluation by a physician or LIP within one hour; or alternatively, 2) allow Registered Nurses to conduct evaluations with telephone consultation from physicians, or 3) require certification for Registered Nurses who initiate restraint and seclusion, or, 4) for rural facilities, allow a waiver process based on the level of physician coverage available to a facility, so that smaller, rural facilities can develop alternative means of evaluation.

(Submitted by Steve Brennan, System Director, Advocacy & Public Policy, Providence Health System)

EMTALA

1. Advanced Beneficiary Notices (42 CFR 411.406) and (42 CFR 49.24(a)): The collection of Advanced Beneficiary Notices (ABNs), required at the time of registration, necessitates considerable time and effort on the part of hospital staff, particularly since they must be collected prior to providing service to a beneficiary. It is difficult for hospital staff to know when stabilization has occurred and whether there is a determination of medical necessity. This is exacerbated by the fact that hospitals must also contend with Local Medical Review Policies (LMRPs). This is both a

resource drain and a source of patient dissatisfaction; patients are upset when their physician orders a treatment and the hospital informs them they may be required to pay the bill.

Recommendation: CMS should clarify this rule to give improved guidance to both providers and Fiscal Intermediaries as to which situations require ABNs be collected. Providing greater clarity on how to proceed under such circumstances would allow providers to meet both the ABN requirement and EMTALA (Section 1867 of the Social Security Act; 42 CFR 49.24(a)). As an alternative, CMS should explore a requirement that FI's maintain a call center for ABN questions so that coverage questions can be answered prior to completion of the ABN.

(Submitted by Steve Brennan, System Director, Advocacy & Public Policy, Providence Health System)

2. Emergency services needed to stabilize patients should be exempt from denials under local medical review policies (LMRPs) (42 CFR 421.100(a) and 42 CFR 489.24). If a hospital participates in the Medicare program, it is required to screen any individual who comes to the emergency department to determine whether that person has an emergency medical condition and, if so, to stabilize him or her. A hospital must use any ancillary services needed to adequately screen and stabilize patients to the extent that such services are routinely available to the emergency department. However, Medicare sometimes denies payment for the services furnished in the emergency department because they exceed LMRPs or utilization guidelines for coverage and frequency established by the Medicare fiscal intermediaries. Hospitals cannot bill beneficiaries for such services unless they notify patients in advance that it may not be covered (*see Advanced Beneficiary Notices*), and they cannot notify patients in advance because the Inspector General interprets Medicare law as prohibiting any delay in screening and stabilization to notify beneficiaries of possible non-coverage.

Recommendation: Section 1867 of the Social Security Act, mandates that hospitals provide all necessary services for emergency screening and stabilization. Medicare should pay for all services a hospital is obligated to furnish, without regard to the local medical review policies (LMRPs) of its contractors. In order to reconcile these conflicting requirements, services furnished in the emergency department should be exempt from claims denials based on LMRPs, and Medicare should pay for *all* services necessary to screen and stabilize patients.

(Submitted by Steve Brennan, System Director, Advocacy & Public Policy, Providence Health System)

3. Need for exception for emergency room physician coverage under EMTALA. Pursuant to state licensing requirements and the Emergency Medical Treatment and Active Labor Act, 42 U.S.C. _ 1395 dd ("EMTALA"), hospital emergency departments must maintain a roster of physician specialists who will be available at all time for consultation with emergency physicians. Hospitals must rely on physicians on the hospital medical staff to provide emergency room coverage and care in order to meet the requirements of these statutes. In addition, many patients who present to hospital emergency departments for care are uninsured, indigent and many have no physician who can provide the required care in the emergency room. Hospitals must arrange for a physician to come to the emergency department to treat the patients who come to the hospital for emergency care. Many physicians who are members of the medical staff at the hospital are unwilling to provide coverage in the emergency room or to come to the hospital to treat those patients who are uninsured, indigent or not yet established with a physician on the medical staff. Hospitals have been forced to

attempt to contract with physicians on the hospital's medical staff so that the hospital can provide compensation to physicians who are willing to provide call coverage in the emergency department and for those physicians who are willing to provide physician services to uninsured and indigent patients. It is often difficult to anticipate which physicians on the hospital's medical staff will agree

to provide these services and physicians are frequently requested to come to the emergency department to provide patient care services before the hospital can establish a written agreement with the physicians or in some instances, the physician is unwilling to enter into a contract with the hospital (There is no incentive for the physician to sign an agreement since the risk of the Stark Law falls upon the hospital). It is a significant burden on hospitals that must provide emergency department physician coverage and on the physicians on the medical staff because written agreements need to be put in place with a large number of physicians in order to comply with the Stark Law. Access to health care is also affected because physicians are unwilling to provide emergency room coverage and patient care services if the hospitals do not compensate the physician for these services.

Potential Solution -- Create an exception to allow a hospital to compensate a physician for providing call coverage services to the hospital's emergency room and for providing professional services to the hospital's indigent and uninsured patients. Language for the exemption might read as follows: "Physician Services provided in the Emergency Room. Compensation resulting from an arrangement between an entity and a physician for the provision of services by the physician in the entity's emergency room in the form of call coverage as required by applicable state and federal law or for physician services provided to the entity's indigent and/or uninsured patients if the arrangement meets the following conditions:

- (1) The arrangement is set out in writing, signed by the parties, pursuant to the personal service arrangements in 42 USCS 1395nn (e) (3) (A), OR
- (2) If a written agreement is not in place for the services provided by the physician at the time that services are performed in the emergency department, then the arrangement meets the terms of a written policy approved by the entity's medical staff and governing board which covers the identifiable services and the fixed compensation to be paid to the physician for providing the identified services.

How Solution Maintains Original Intent Of Statute -- Compensation made to physicians providing emergency room on-call coverage and patient care services to indigent and uninsured patients is not intended to abuse the law's policy. These compensation arrangements are intended only to help the hospital meet its licensing requirements and to ensure access to health care for uninsured and low income patients who present to the hospital with an emergent medical condition. Additionally, if the true spirit of the Stark Law is to prevent abuse of the referral process, patients in the emergency room would pose little threat of abuse - neither the hospital nor the physician can influence the volume of patients. The suggested exemption would just provide for less burdensome patient access and care.

Citation of the Regulation Involved --

42 CFR Part 411.357 Exceptions to the referral prohibition related to compensation arrangements. There is no current exception applicable to emergency room physician coverage.

Citation of the Relevant Statute --

42 USCS 1395 nn: Limitation on certain physician referrals.

(Submitted by Shelly Schlenker, Catholic Healthcare West, Sacramento, CA)

4. On Call List of Physicians at Small Hospitals. On call lists are appropriate to assuring that the emergency department is aware of which physicians, including specialists, are available to provide treatment necessary to stabilize individuals with emergency medical conditions. The interpretive guidelines to surveyors state that "if a hospital offers a service to the public the service should be available through on-call coverage of the emergency department."

In general, this may be a workable requirement. It is not a workable requirement where there are, say, four specialists who practice at the hospital, each of whom resides over 30 minutes away from the hospital. Under this set of facts these specialist physicians are repeatedly called to provide care to emergency patients, an extremely burdensome requirement on these physicians, especially in inclement winter weather. This scenario, which is real at one of our hospitals, prohibits the hospital from being able to transfer the patient to another hospital to receive services when such a transfer is the best means for assuring that the individual presenting to the emergency room receives the care he/she needs. We recommend that the interpretive guidelines be modified to permit flexibility to rural hospitals to transfer patients when the specialist physicians are subject to burdensome on-call responsibilities.

(Submitted by Nancy A. Baerwaldt, Vice President, Advocacy, Trinity Health)

5. Redirection Of Patients Before Presenting At The Hospital For Emergency Care. Guidance to surveyors provides that if a hospital that is not in diversion status does not accept a request for admission, the refusal could represent a violation. Flexibility in the interpretive guidelines is required to assure that patients in transit via an ambulance are taken to the nearest appropriate hospitals that are able to meet their needs. If this flexibility is not provided patients will not receive the best screening to which they are entitled.

(Submitted by Nancy A. Baerwaldt, Vice President, Advocacy, Trinity Health)

6. EMTALA -- Paperwork before Patient Care

(excerpt from Margaret Barron testimony at January 7 Advisory Commission Hearing)

One of the other areas that we have is the EMTALA Act, the Emergency Medical Treatment and Active Labor Act, known to some of you earlier as COBRA. This was the anti-dumping law, which is now -- I think 1988 it started, 1987. Again, it was a good idea, it was a patient care issue. Bad things were happening to patients in emergency departments. But it's gone way too far again. The interpretation and application are overly broad.

A couple of years ago they decided that this act applies to any facility the hospital operates within -- I can't remember if it's a 5- or 10-mile radius. For example, we operate a clinic down on M Street, and they're about two miles from here. If a patient walks into clinic and they say, "I don't feel good," and they think the patient is having a heart attack, theoretically they're supposed to call me in the emergency department and arrange a transfer, get an accepting physician. Now, if they're calling me and it's my facility, no problem, they don't have to do that. They can get an ambulance and send the patient to me.

But that's not the closest hospital. The closest hospital is GW, and it makes more sense to pick up the phone and call 911, get the paramedics there and take them to the closest hospital. But if they do that without first calling GW, getting an accepting physician, they're in violation of the EMTALA Act. There's a ton of paperwork that's supposed to be filled out before the patient leaves, a copy of the chart, et cetera. Well, the paramedics are there and gone before that stuff is done, but you want me to sit there and wait while I fill out the paperwork.

There are some common sense aspects of EMTALA that have been completely bypassed. Another good example is the anthrax epidemic, and I call it an epidemic because it affected far more than the people who actually came down with anthrax. In the midst of all that, we had 170 patients in our department that first day after the announcement. I couldn't triage them away. I had to see every one of them, do the medical screening exam, even though they were there to say, "I just want to be tested for anthrax, I think I have anthrax." There's a difference, "I want to be tested for anthrax" versus "I think I have anthrax."

We couldn't send people away because of that Act. They had to be seen by a licensed person, independently licensed, either a physician or a physician assistant or a nurse practitioner. They had to have the medical screening exam done, and then we could say you're fine. But that's just an example that during a time of crisis that we couldn't use common sense and send people out and say follow up with your doctor. We couldn't even take care of the genuinely sick people we had that day, we were so overwhelmed. So EMTALA is another act that's got a lot of paperwork and regulation to it.

(Submitted by Dr. Margaret Barron, MD, Providence Hospital, Washington, DC)

EMTALA con't.

The following 5 issues were identified and submitted by Bon Secours Health System, Inc. as preliminary comments on proposed changes to EMTALA Regulations Published in the Notice of Proposed Rule Making ("NPRM") Issued May 9, 2002

1. Clarification of "Comes to the Emergency Department"

- A. Issue -- By expanding the definition of "hospital property" to include off-campus hospital departments, the current EMTALA rule imposes patient care obligations on providers that are often not adequately trained or equipped to address emergency medical situations. Changes proposed in the NPRM to eliminate the application of EMTALA to off campus departments of a hospital are greatly welcomed. Furthermore, the proposed changes ensure that patients presenting at off-campus locations with an emergency medical condition receive prompt emergency care from emergency medical service provider who are professionals trained to provide such services.
- B. Intent of Current Law or Rule -- Current EMTALA regulations apply EMTALA provisions to off-campus provider based departments of a hospital.
- C. Proposed Reform -- Further revisions are needed to the definition of "dedicated emergency department" that is contained in the NPRM to make it clear that EMTALA only applies to emergency departments staffed and specially equipped to provide true emergency (as opposed to urgent) care. Urgent care centers that see patients on a non-appointment basis should not be included in the definition of a "dedicated emergency department." "Urgent care centers" are neither specially equipped nor appropriately staffed to address emergency medical conditions. Bon Secours recommends that the definition of "dedicated emergency

department” not be based on the number of patients seen, but on whether or not the department is specially equipped and staffed to provide emergency care and holds itself out as a provider of emergency services. If, however, emergency care is provided in any department of a hospital on a routine basis other than in the ED, such as labor and delivery or psychiatry, then those departments should be considered to fall within the definition of dedicated emergency department and subject to EMTALA.

D. Who would be Affected? -- Hospital providers.

2. On-Call Provisions in the Proposed Rule

- A. Issue -- Hospital entities are having increased difficulty in ensuring adequate emergency department coverage for a variety of specialties. The NPRM is helpful in that it clarifies that there is no regulatory requirement that a hospital maintain an on-call list that ensures 24 hours a day, 7 days a week coverage merely because a hospital has 3 physicians in a particular service or specialty. Certain language contained in the NPRM is, however, overly vague and subject to varying interpretations.
- B. Background -- Healthcare facilities are facing increased difficulty in maintaining physician on-call schedules. This is especially true of the physician specialties such as neurosurgery, orthopedics, and psychiatry and in inner city and rural settings. Clarification that there is no regulatory requirement that a facility maintain an on-call list that ensures 24 hours a day, 7 days a week coverage merely because a hospital has 3 physicians in a particular service or specialty is helpful.
- C. Intent of Current Law or Rule -- To ensure adequate specialists are available to provide emergency care to patients, regardless of the patient's ability to pay.
- D. Proposed Reform -- The proposed rule as contained in the NPRM should be revised to eliminate the language which provides that a hospital maintain a call list in a “manner that best meets the needs of the hospital's patients.” The rule should merely state that: (i) a hospital must maintain an on-call list; (ii) 24 hours a day, seven days a week coverage in any specialty is not required; and (iii) hospitals must have policies and procedures in place to respond to situations when there is no physician on-call, the physician refuses to go to the hospital, or the physician fails to respond in a reasonable period of time. The “best needs” language is overly vague and would be subject to varying interpretations by facilities, state regulators, as well as plaintiffs' attorneys.
- E. Who would be Affected? -- Hospital providers and physicians

3. Applicability of EMTALA to Individuals Who Come to the Emergency Department for Nonemergency Services.

- A. Issue -- When an individual comes to the ED, a health care practitioner should be permitted, based on his or her medical judgment, to make a determination that the individual does not have an emergency medical condition and then refer the individual to a more appropriate care setting
- B. Background -- Overcrowding in emergency departments is being exacerbated by the large number of nonemergency patients combined with a hospital's concern that EMTALA prevents a facility from referring nonemergency patients to a more appropriate level of care.
- C. Proposed Reform -- The proposed rule should be revised to make it more clear that an individual appearing for a clearly non-emergent medical condition, as determined by a medical practitioner, can be referred to a more appropriate level of care.

D. Who would be Affected? -- Hospital providers.

3. Application of EMTALA to Inpatients

- A. Issue -- There has been an ongoing legal debate regarding whether a hospital's EMTALA obligations extend to inpatients of the hospital.
- B. Intent of Current Law or Rule -- Current EMTALA rules do not address this issue.
- C. Proposed Reform -- The proposed regulations are helpful in that they clarify a facility's EMTALA obligations when a patient is an inpatient of the facility. The rule should be further expanded to make clear that EMTALA does not apply to any patients who are a "direct admit" to the facility regardless of whether they arrive at the facility in a stable or emergency condition or whether they arrive by ambulance or private vehicle.
- D. Who would be Affected? -- Hospital providers

4. Psychiatric Patients

- A. Issue -- There have been questions raised by hospital providers as to when a psychiatric patient is considered stable for discharge or transfer.
- B. Background -- Several hospital providers have been cited for discharging or transferring psychiatric patients regulators felt were unstable.
- C. Intent of Current Law or Rule -- Current regulations do not adequately address when a psychiatric patient is considered stable for discharge or transfer.
- D. Proposed Reform -- The proposed regulations do not address this issue. Bon Secours recommends that CMS provide more detailed guidance on when a psychiatric patient is stable for either discharge or transfer.
- E. Who would be Affected?-- Hospital providers

(for further information, contact Sherry Brunner, Vice President for Risk Management and Loss Prevention, or Maggie Costella, Director of Legal Affairs, at Bon Secours Health System, Inc., Marriottsville, MD)

Stark Law

1. Interpretation of "set in advance" percentage compensation arrangements under Stark II exceptions (42 CFR 411.354 (d)(1)): CMS indicated that compensation will not be considered "set in advance" for purposes of the Stark Law's exceptions if the compensation arrangement is based on "fluctuating or indeterminate measures," such as percentage compensation arrangements (See 66 FR 856 at 959). However, this interpretation – which was to become effective as of January 4, 2002 – was delayed by CMS until January 6, 2003. See 66 FR 60154.

Recommendation: We suggest that the "set in advance" standard for purposes of the Stark Law should be satisfied where a formula that renders certain the calculation of actual compensation is established ahead of time (i.e., is set in advance), and that formula does not change over the term of the arrangement. For example, a formula that compensates a physician or medical group based on a percentage of collections should satisfy the "set in advance" standard--assuming (i) it contains sufficient detail so that correct and accurate payment under the formula may be verified; (ii) that the actual payments made under the formula are consistent with the fair market value of the services or items furnished thereunder; and (iii) that the formula does not change during the term of the arrangement based on any factors (including specifically the volume or value of referrals between

the parties). This revised interpretation of the "set in advance" standard would also be consistent with CMS' position that "per-use" or "per-service" arrangements satisfy the "set in advance" standard where the above conditions are met (*See* 66 FR 856 at 959).

(Submitted by Steve Brennan, System Director, Advocacy & Public Policy, Providence Health System)

2. Adverse impact on California medical foundations of exceptions to Stark Law regulations dealing with "set in advance" compensation. CMS's definition that compensation expressed as a percentage of revenues, receipts, expenses or profits is not "set in advance" for purposes of the personal services and fair market value exceptions to the Stark Law has a severe, negative impact on the relationships California's integrated health systems (including Catholic Healthcare West) have with their physicians and will most likely result in the unwinding of most California medical foundations. The unwinding of the medical foundation model will occur despite the fact there is no abusive practice associated with such percentage arrangements, especially where the percentage is set in advance and doesn't change for a term of one year, and the revenues on which the percentage is based explicitly excludes revenues from designated health services.

California's ban on the corporate practice of medicine prevents laypersons, including hospitals, from hiring physicians or forming medical groups. California does, however, permit qualifying charitable organizations known as medical foundations to engage medical groups under a professional service agreement to care for the foundation's patients. In essence, California medical foundations provide physician services to their patients through professional service agreements with medical groups. Since most other lay entities are generally prohibited from directly or indirectly providing physician services, medical foundations are important to the health care delivery system in California. Medical foundations create a vehicle to develop integrated delivery models that allow for the synergistic delivery of care (coordinated care across various providers) that helps the patient.

Due to the corporate practice prohibition, California medical foundations are unable to use the Stark Law's employment exception, as is widely the case throughout the country. Accordingly, medical foundations are heavily dependent on the personal service exception to the Stark Law, which will be augmented by the fair market value exception once it takes effect next year. To comply with either of these two exceptions, compensation must be set in advance, reflect the fair market value of the services and cannot vary with the volume or value of referral or other business generated between the parties.

The problem is simply this - under the regulations, compensation cannot be "set in advance" if it is percentage based. CMS has defined "set in advance" to include formulas that pay physicians for each service rendered ("per service compensation" which are equally variable), but not those that are percentage based.

California medical foundations compensate medical groups based on a percentage of the foundation's physician service revenue, including capitated revenue. These agreements generally do not pay physicians any portion of the revenue the foundation derives from providing designated health services. By basing compensation on a formula set in advance that pays physicians based solely on physician service revenue, foundations have sought to comply with requirements of the personal service exception, especially the key requirements that compensation be set in advance and not vary with the volume or value of referrals.

In a volatile, heavily managed care penetrated market such as exists in California, percentage arrangements are the only method available to California medical foundations to manage the risk of decreasing payor reimbursement. Percentage arrangements are the only method that allows the foundation's payment to physicians to vary with the reimbursement rates paid by key third-party payors during the year. Providers who are largely paid on a capitated basis, such as California medical foundations, use percentage compensation arrangements, typically percentage of revenue, to better align physician and foundation interests to respond to the challenges posed by capitation.

Integrated delivery systems with the Foundation model will be forced to unwind their relationships with their physicians, thereby disrupting an already vulnerable system. As integrated health systems unwind their relationships with medical foundations, it will be the patients who will be most impacted. In the case of the CHW Medical Foundation, what is now one medical group, with integrated primary and specialty care, would likely break into five or six medical groups. The patients would have to negotiate a much more complex system to receive care - not to mention deal with trying to coordinate their insurance authorizations. An increase in costs and higher levels of frustration among patients are easily foreseeable results of the percentage compensation prohibition.

Potential Solution -- Revise the Phase I Stark Law regulations to define "set in advance" to permit percentage compensation arrangements. This can be accomplished by simply deleting the last sentence of 42 CFR 411.354 (d).

Citation of the Regulation Involved --

42 CFR Part 411.354 Financial relationship, compensation, and ownership of investment interest. 411.354 (d) Special rules on compensation. The following rules apply only to compensation under section 1877 of the Act and these regulations in subpart J of this part.

(1) Compensation will be considered "set in advance" if the aggregate compensation or a time-based or per unit of service-based (whether per-use or per-service) amount is set in advance in the initial agreement between the parties in sufficient detail so that it can be objectively verified. The payment amount must be fair market value compensation for services or items actually provided, not taking into account the volume or value of referrals or other business generated by the referring physician at the time of the initial agreement or during the term or the agreement. Percentage compensation arrangements do not constitute compensation that is "set in advance" in which the percentage compensation is based on fluctuating or indeterminate measures or in which the arrangement results in the seller receiving different payment amounts for the same service from the same purchaser.

Citation of the Relevant Statute

42 USCS 1395 nn: Limitation on certain physician referrals.

(e) Exceptions relating to other compensation arrangements.

(Submitted by Shelly Schlenker, Catholic Healthcare West, Sacramento, CA)

3. The Prepaid Plan Exception to the Stark Law is broad and applies to any referrals of managed care patients covered by federal health programs made by providers downstream of a managed care contract. Thus, referrals of managed care enrollees by physicians to other entities down stream from

the payor are exempt from the Stark Law. The Prepaid Plan Exception does not, however, except the financial relationship whereby a physician may provide managed care services to Hospital or Hospital Subsidiaries' (Hospital) patients. As a result, any financial relationship (including between downstream providers) may need to be excepted if a physician also refers non-managed care patients for Direct Health Services. A separate exception for the financial relationship arising from the provision of managed care services is needed to except these Direct Health Service referrals. It is difficult, and often impossible, to put a prior written agreement in place with non-contracted physicians prior to their provision of services.

Hospitals and Hospital subsidiaries (Hospitals) often enter into pre-paid capitation arrangements with HMOs under which Hospitals are obligated to provide a broad range of services and specialties across a wide geographic area to covered patients. The contracted providers of Hospitals cannot furnish all of the services required under these pre-paid capitation arrangements. Consequently, Hospitals are obligated to pay providers who render services for patients for whom Hospitals have a contract with these providers. Hospitals negotiate written agreements with providers, including physicians, who can be anticipated to provide services to Hospitals' patients. In some instances, however, Hospitals are unable to enter into a written agreement with the physician rendering the services to a covered patient prior to the provision of services. Reasons why Hospitals may not be able to obtain a prior written agreement with the service provider include, but are not limited to, the following:

- (1) When a managed care patient visits any emergency room, the Emergency Medical Treatment and Active Labor Act, 42 U.S.C. _ 139dd ("EMTALA), precludes emergency room staff from obtaining patient insurance information prior to services being rendered. Consequently, when an emergency room physician determines that a patient needs to receive care from a specialist, the physician refers the patient to a physician in that specialty who may or may not be a contracting physician with the Hospital;
- (2) When a managed care patient is referred to a surgeon, the surgeon selects physicians to assist with the surgery. The physicians assisting in the surgery may or may not be contracting physicians with Hospitals;
- (3) Physicians may leave or terminate their contracts with medical groups or Independent Physician Associations ("IPAs) without first notifying Hospitals accordingly, Hospitals believe that they have a contract with that physician through their medical group or IPA, only to learn after the services are rendered and billed that they do not have such contracts.
- (4) When an HMO patient transfers involuntarily from one medical group to another medical group (i.e., when a primary care physician transfers from one medical group to another or when a payer agreement between an HMO and medical group is terminated), the new medical group is obligated to allow the HMO patient to maintain a reasonable continuity of care from physicians from which the patient had received care prior to his or her transition to the new medical group. Hospitals may not have written arrangements with these providers.
- (5) Without Hospitals' knowledge, managed care patients may be referred to physicians with a request to provide services for which Hospitals are contractually bound (by terms of their contracts with HMOs or other third party payors) to reimburse physicians. This situation occurs primarily

when an out-of-network physician refers a managed care patient to another out-of-network physician without obtaining a referral from Hospitals.

(6) Hospitals may be responsible for purchasing out-of-area emergency services received by managed care enrollees. Under some HMO agreements, out-of-area emergency services includes services provided anywhere in the United States and internationally. It is impractical to obtain contracts with such a broad geographical scope. It would also be impractical to obtain contracts with all physicians on CHW medical staffs. In some instances, due to specialty magnet services provided, these out-area-physicians may still be considered a referral source.

Potential Solutions -- All referrals to downstream providers by the network managed care organization's providers for Designated Health Services, whether for pre-paid patients or for fee-for-service patients, should be protected under the prepaid plan exception so that referrals of plan enrollees do not impact the ability of physicians/hospitals to provide services to fee-for-service patients.

Citation of the Regulation Involved –

42 CFR Part 411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.

411.355 (c) Services furnished by an organization (or its contractors or subcontractors) or enrollees to one of the following prepaid health plans (not including services provided to enrollees in any other plan or line of business offered or administered by the same organization). (Sections (1) (2) (3) (4) and (5) Health plan descriptions not included).

Citation of the Relevant Statute --

42 USCS 1395 nn: Limitation on certain physician referrals.

(b) General exceptions to both ownership and compensation arrangement prohibitions.

(3) Prepaid plans. In the case of services furnished by an organization –

(Submitted by Shelly Schlenker, Catholic Healthcare West, Sacramento, CA)

Coordination

New Technology Coverage (FDA/CMS)

1. Timely Inclusion of new technology in Medicare Coverage (42 CFR Parts 412.87 and 412.88) and (42 CFR Parts 413, 419 and 489): In many segments of the health care delivery system, new developments in technology, including both equipment, procedures and drugs, have dramatically improved the efficacy of treatments for medical conditions. New technologies, for example, are radically transforming cancer care and cardiology – two of the most common categories of treatment for Medicare beneficiaries. As these new technologies become more mainstream, public demand for them increases. However, CMS has been notoriously slow to incorporate these new technologies into its payment structure. This creates a situation in which hospitals and outpatient facilities must invest in new technologies to meet demand, yet receive little or no Medicare reimbursement for long periods of time.

Recommendation: Responding to the requirements of Section 533 of the Public Law 106-554, the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act (BIPA), CMS published a final rule on Sept. 7, 2001 making changes in the current system to incorporate new technologies into the inpatient DRG structure. We encourage CMS to continue to refine an effective “fast-track” mechanism for evaluating new technologies and, if merited, incorporating them into inpatient and outpatient payment calculations. Additionally, we recommend that CMS identify ways to more equitably address the spending cap on pass-through payments for new devices and biologicals to relieve the burden on rural outpatient facilities and those that are not high users of new technologies.

(Submitted by Steve Brennan, System Director, Advocacy & Public Policy, Providence Health System)

2. Recognition of technology costs in all-inclusive rates for post-acute care (42 CFR 413 Subpart J, 42 CFR 412.624 and 42 CFR 484.220): New technologies are saving lives and improving the quality of life not only for patients treated in the hospital or outpatient facility, but also in Skilled Nursing Facilities, rehabilitation units and home health care. The current Prospective Payment Systems, established by Sections 1888(e), Section 1895 and Section 1886(j) of the Social Security Act, are based on data and technology that is over four years old. There are no regulatory mechanisms in place to adjust the PPS when these new technologies arrive and yet, it is EXPECTED, as it should be, that these products, supplies or services be rendered. It should also be expected that the costs of these new technologies are covered and yet, there are no built in systems to change the payment facilities receive for these new products. Instead, it is expected that the facility absorb the costs. It is an unrealistic and unfair expectation.

Recommendation: We propose that accepted new technologies that carry a high price tag be "excluded" from the PPS and reimbursed on a fee schedule basis until such time as CMS can incorporate their cost into the all-inclusive rate.

(Submitted by Steve Brennan, System Director, Advocacy & Public Policy, Providence Health System)

State/Federal

Regulatory Process Reforms: Understanding and complying with the numerous federal and state agencies that regulate the health care system pose an enormous and, at times, unreasonable burden on hospitals and other providers. This is particularly true when CMS, the most significant regulator of providers, frequently promulgates rules without coordinating implementation dates with other federal agencies or provides scant time for providers and Fiscal Intermediaries to understand and comply with them. For example, CMS proceeded forward with its implementation schedule for the Medicare Outpatient Prospective Payment System even as its own internal software systems were not yet finished.

Recommendations: We recommend the following changes:
Increase stakeholder participation in rulemaking – Under Section 1871 of the Social Security Act, CMS is required to follow a meet several timelines when proposing and adopting rule changes. CMS can, within the spirit of Section 1871, increase its emphasis on negotiated rulemaking and provide greater opportunity for provider input early in the development process – prior to publishing interim final rules or before proposed rules are published. This should include regional field hearings, on-site consultations with providers, as well as publicly release databases, cost estimates, assumptions and methodologies at the time notice is given.

(Submitted by Steve Brennan, System Director, Advocacy & Public Policy, Providence Health System)

Timeliness of Regulatory Promulgations

Timeliness of Regulatory Promulgations. CMS permits inordinate and inappropriate amounts of time to pass between the promulgation of proposed rules and the promulgation of final rules. The industry is often allowed only 60 days – and sometimes just 30 days – to comment on voluminous, detailed and complex regulations, yet CMS often permits *years* to pass before a final regulation is issued. Examples include:

- The Home Health Agency Conditions of Participation: proposed rules were promulgated March 10, 1997; industry comments were required to be submitted by May, 1997. Final rules are still to be promulgated, **five years later**.
- The Hospital Conditions of Participation: proposed rules were promulgated on December 19, 1997; industry comments were required to be submitted by February, 1998. Final rules are still to be promulgated, **four years later**.
- The HIPAA Security Regulations were promulgated August 12, 1998. Industry comments were due by October 13, 1998. Final regulations are now promised for August 2002, **over three and a half years later**.
- The Laboratory Services Conditions of Participation (Hepatitis C Look-back): proposed rules were promulgated November 16, 2000; industry comments were due by January 15, 2001. Final rules are still to be promulgated, **one and a half years later**.
- The Life Safety Conditions of Participation: proposed rules were promulgated October 26, 2001; industry comments were due by December 26, 2001. Final rules are still to be promulgated, **one and one half years later**.
- Stark II (Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships) regulations: proposed regulations were promulgated January 9, 1998; industry comments were due by March 10, 1998. Final regulations (Part A) were promulgated January 4,

2001, with a now-deferred effective date of January 3, 2003. Part B of the final regulations are still pending, **over four years since the initial regulatory promulgation (and over 9 years since the legislation requiring the regulations was passed).**

Failure to act in a timely fashion delays much needed guidance, and harms beneficiaries by denying needed benefit enhancements or regulatory protections in a responsible and responsive manner. Inordinate delays harm providers by making it impossible to plan effective, timely training on regulatory changes. Training provided in the rushed 60-day implementation period after a final regulation is issued is often of little lasting value and must be repeated, at considerable additional costs to all involved. Overriding goals of CMS regulatory practice should include fairness, fidelity to the authorizing legislation, and transparency and predictability of regulatory processes. The recent move to a single promulgation date monthly is a good first step, but more needs to be done. While a semi-annual schedule of expected promulgations also assists a little in longer-term planning, providers are still significantly hampered by the 60-day implementation period for large, significant changes in complex regulations.

Recommendations: CMS should require itself to issue final regulations within 90 days of the close of public comment periods; and if CMS determines that additional deliberation (beyond 90 days) is needed on matters raised in the comments received, CMS should require itself to identify with specificity those matters under additional review through revised proposed rulemaking by the 90th day after the close of the initial comment period. CMS should invite additional industry comment for 30 days on such limited matters for additional deliberations to ensure that CMS receives appropriate input from providers and beneficiaries on difficult and contentious issues. CMS would then have 60 days to issue the final regulations after the close of the second comment period. In no event should any proposed regulation remain in limbo longer than 5 months from the date of initial promulgation (where no additional deliberation is required) or 8 months from the date of promulgation of the proposed regulation, where an additional comment period for is necessary for additional deliberation. CMS should also require itself, as a matter of public responsiveness and administrative efficiency, to withdraw from proposed rulemaking status any proposed regulation that is not finalized within 8 months of promulgation as a proposed rule and re-start the rulemaking process from the beginning.

Finally, CMS should expand the current web-site listing of pending regulatory guidance to include ALL proposed rulemaking which is not yet finalized. The current website is incomplete and only goes back to May, 2000. Providers, beneficiaries and Congress need to see at a single site, all proposed rule-making that is in process. Such a listing would provide an important sign of increased accountability by CMS and would provide a real-time measure of CMS' ability to meet responsiveness deadlines.

(submitted by Donald E. Koenig, Vice President, Corporate Responsibility, Catholic Healthcare Partners; Cincinnati, OH)

Other Provider-Specific Issues

Nursing Facilities

Need to allow for short-term rehab and eliminate three-day hospital stay requirement. Gait abnormality is a common diagnosis for elderly who develop an acute illness. It effects their ability to perform their activities of daily living. In medical terms, it does not stand as a serious condition but for any elderly person effected by a sudden loss of their independence on ADLs. This is a major complication of simple illness such as UTI and bronchitis or even a fall and back pain. The need for a short-term rehab or assistance with ADLs until the elderly patient returns to baseline is now only met by an admission to the hospital. A three-day stay in the hospital is also necessary before the elderly patient can be transferred to a lesser level of care in a SNF. Skilled nursing facilities should be able to admit elderly patients in need for short-term rehab and nursing care directly or after a 23-hour observation admission to a hospital. It is the right thing to do medically and I dare say economically. Patients with adequate support at home, who can receive outpatient care would of course be excluded as they already are when evaluated in emergency rooms.

(Submitted by Jabbar Fazeli, MD, Sisters of Charity Health System, ME)

Rural Health

1. Rural Health Clinic Employment Relationships. (CFR 491.8(a) (3)) Rural Health Clinic (RHC) regulations should be modified to eliminate the requirement that physician assistants, etc. be employees of hospital-based RHCs. Were this desired change made, care continuity and integration would be enhanced in rural areas, especially in rural areas in which hospitals and other facilities have organized themselves into systems of care.

(Submitted by Nancy A. Baerwaldt, Vice President, Advocacy, Trinity Health)

2. Extension beyond January 1, 2004 for small rural hospitals (fewer than 100 beds) of the exemption from the Hospital Outpatient PPS.

I believe that Congress would have to make this exception. However, if the Administration were in support of such a regulatory change, that would be helpful. These small rural hospitals should be spared from these new regulations.

(Submitted by Nancy A. Baerwaldt, Vice President, Advocacy, Trinity Health)

3. Employment of Mid-Level Practitioners at Rural Health Clinics.

“Rural Health Clinic” (RHC) is defined pursuant to regulations as “*a clinic that is located in a rural area designated as a shortage area*” (§491.2). Additionally, the regulations require that a provider-based RHC must be operated as “*an integrated and subordinate part of a hospital ... and ... operated with other departments of the provider under common licensure, governance and professional supervision*” ((§405.2462[a][1]-[2])).

Some health systems operating as integrated delivery networks (IDN) have under their employ physicians and physician's assistants who provide care at numerous locations within the integrated delivery network, including RHCs. Having physicians and physician's assistants employed by the health care system is desirable for at least the following reasons:

- ① Better continuity of care, higher quality services, and the "professional supervision" that is required pursuant to the regulations.
- ② More efficiency and greater cost containment.

We understand that the Centers for Medicare and Medicaid Services (CMS) has asserted that a physician's assistant who provides care at an RHC must be an employee of the RHC – even those RHCs that are **provider based** -- and may not be an employee of the IDN. In making this conclusion, the CMS points to §491.8(a)(3). It reads:

"The physician assistant, nurse practitioner, nurse mid-wife, clinical social worker, or clinical psychologist member of the staff may be the owner or an employee of the clinic, or may furnish services under contract to the center."

The word "center" in this regulation does *not* mean RHC. Instead it means a Federally Qualified Health Center (FQHC). In other words, an FQHC may contract for, i.e., need not employ, the services of a physician's assistant. However, CMS, citing this rule, asserts that an RHC must have the physician's assistant under its employ.

This interpretation may be appropriate for freestanding RHCs. However, it is not appropriate for **provider-based** RHCs. For **provider-based** RHCs, continuity of care and quality of services are enhanced, as well as delivered at lower cost, when the physician's assistant is employed by the IDN.

I would also point to §405.2414(a), which reads:

"Professional services are reimbursable under this subpart if: (1) Furnished by a ...physician assistant...who is employed by, or receives compensation from, the rural health clinic"

This language, which is in the section of the CFR that sets forth general requirements for both an RHC and an FQHC, permits reimbursement to a physician's assistant who provides services under contract with an RHC without being its employee.

Notwithstanding §405.2414(a) CMS requires that each of its Medicare-certified RHCs have under their employ (the "RHC W-2 requirement") physician assistants who render patient care at RHCs. This "RHC W-2 requirement" may be appropriate for freestanding RHCs that are not owned or operated by a hospital. However, this "RHC W-2 requirement" is not appropriate for **provider-based** Medicare-certified RHCs.

(Submitted by Nancy A. Baerwaldt, Vice President, Advocacy, Trinity Health)

Other Providers Issues

1. Application Process. Almost 2 months was spent trying to get the application completed, correct signatures, copies of licenses, insurance, Board of Directors, etc. During the process of getting the first number, the form was returned 2 months later with a request for the birth dates of the Board of Directors and their social security numbers. (This was never requested anywhere on the original form.) Finally, after about 4 more months, the first number was approved for Mercy Franklin Apothecary. The application process for the second Medicare number for Mercy Specialty Care Pharmacy was begun. Knowing it would take quite a while for the application to be processed, we waited about 2 months and then began calling the hot line. The hot line said the request was approved and the application closed and on file. However, notification of the new number was never received. After calling every 3 to 4 weeks for about a year, I was finally given the number for the ombudsman. Everyone spoken with during the previous conversations had said they were not sure what had happened and they would contact their manager and call me back. It was finally learned that the second application had been used to change the information on the first Medicare provider number (issued to Mercy Franklin Apothecary) to Mercy Specialty Care Pharmacy. It would seem that if one is licensed with the Drug Enforcement Administration and the State Board of Pharmacy, the application process could be shortened.

(submitted by Carmela Brown, Government Relations, Mercy Medical Center, Des Moines, IA)

2. Medicare Federal Health Care Provider/Supplier Enrollment Application.

The 67-page Medicare provider application form is an example of an overly inclusive and overly burdensome form. The information required could be easily secured with a 4-page application.

(Submitted by Nancy A. Baerwaldt, Vice President, Advocacy, Trinity Health)

3. CRNAs Medicare Regulations.

The Medicare rules and regulations as they relate to CRNAs unnecessarily restrict their practice. Specifically, in order for an anesthesiologist to receive Medicare reimbursement he/she must fulfill several conditions of participation (all of which a CRNA is competent in doing and is within their scope of practice). Some of these conditions are:

- 1) perform a pre-op examination
- 2) be present at induction and during difficult portions of the procedure
- 3) check on the progress of the case on a regular basis
- 4) be present at exduction (awakening of the patient)
- 5) monitor patient in PACU
- 6) post-op visit.

This regulation is **not enforceable**. If anesthesiologists were to follow the letter of this requirement, it would be inefficient and not cost effective for an operating room. Specifically, it would cause constant delays in waiting for them to perform the required functions. Additionally, anesthesiologists use these rules to restrict the practice of CRNAs. As such, the regulation leads to an increased cost of care.

(Submitted by Nancy A. Baerwaldt, Vice President, Advocacy, Trinity Health)

Other

Coverage and Reimbursement Issues

1. Bundling Of Medical Supplies: Under the bundling requirements of the home health prospective payment system, agencies are responsible for all needed medical supplies regardless of the reason for home care. For example, a newly diagnosed diabetic may receive home care for stabilization and education for the diabetes. If this patient also has a 20 year old ostomy, the home care agency is responsible to provide ostomy supplies. This requirement has led to a great deal of confusion on the part of beneficiaries and suppliers. The beneficiary may have a 20-year-old relationship with the supplier of ostomy supplies and be on a routine shipping schedule. Now because of the home care agency's involvement with diabetic care, that next routine shipment will be denied Medicare coverage. The supplies provided by the home care agency might be of a different brand than that of the supplier requiring the patient to change a practice that has been familiar for years. Once home care ends, there is a lag in claim submission so that suppliers claims are still kicked out for an open home care episode even after discharge from the home care agency. This requirement has resulted in an unnecessary burden to beneficiaries, agencies, and medical supply companies.

(Submitted by Nancy A. Baerwaldt, Vice President, Advocacy, Trinity Health)

2. Therapy Bundling. The bundling requirement for therapies is confusing. Therapies requiring equipment too large or cumbersome to bring to the home have always been covered apart from the home care benefit. The financial models that were used to develop the home care prospective payment system did not capture these charges as they were paid under Part B. However, under the new system, home care agencies are responsible for these therapies. Because a home care patient is not under the control of the home care agency 24 hours/day, 7 days per week, there are occasions when physicians make arrangements for home care patients to receive therapy services on an outpatient basis. The Medicare conditions as they have been applied to these services require that the home care agency provides services under arrangement and that all documentation rules and personnel rules apply to the outpatient services as if they were rendered in the home. Many times home care agencies are unaware that their patients have begun receiving services as outpatients and thus cannot meet the "under arrangement," and documentation requirements. Patients are also limited to receiving therapy from providers contracted with the home care agency whether or not that provider is the choice of the patient and or physician.

(Submitted by Nancy A. Baerwaldt, Vice President, Advocacy, Trinity Health)

3. Physician Billing for Hospice Patients. Under current regulations, when a hospice patient is seen for symptoms/conditions related to their terminal illness by other than their attending physician, that physician would be considered a consultant. The consultant physician bills the hospice; the hospice bills the Medicare Intermediary (Cahaba) and reimburses the consultant physician the usual/reasonable amount from Medicare. Essentially, hospice is the middleman or a pass through. This process is burdensome in the fact that every time we bill for a consultant physician a contract needs to be in place. It is also burdensome for the hospice agencies because physician billing is complicated and hospice agencies are not a Part B Provider, thus our knowledge and efficiency of the billing process is limited. It is confusing for the billing department of the physician's office

since it is a small amount of their billing business, as compared to their regular volumes. We suggest and advocate that if a hospice patient is seen by any physician, that the physician bills for the patient visit, as they would bill for any other patient visit.

(submitted by Carmela Brown, Government Relations, Mercy Medical Center, Des Moines, IA)

4. Nursing Home Room and Board Payments. Under current practice, when a Medicare/Medicaid recipient receives hospice benefits in a nursing facility, the hospice provider must bill the Medicaid fiscal agent (Consultec) for both the hospice and the nursing facility's components of the patient's care. The hospice is then responsible for reimbursing the nursing facility for the patient's room and board expense. This is a burdensome process, which unduly places the hospice in the position of being the "fiscal intermediary" on behalf of the nursing home. Calculating these payment differences is very complicated and, if done incorrectly, the hospice program could unknowingly violate federal fraud and abuse statutes.

National data from the U.S. Department of Health and Human Services supports the Iowa Hospice Organization's position that the payment system would work more efficiently if hospice and nursing home Medicaid benefits were paid separately, and that "administrative burdens...could be reduced by having the Medicaid program pay the nursing home directly".

The current policy is difficult to process and unfairly places the burden of another industry's payment policies upon hospice providers. This is a policy that Congress should direct the Centers for Medicare and Medicaid Services to change.

(submitted by Carmela Brown, Government Relations, Mercy Medical Center, Des Moines, IA)

5. General Medicare registration and payment collection processes

The Medicare registration process is very time consuming. The required questionnaire asks about other benefits, payers, diagnoses, employment, spouse information - all to determine if there is a payer that is primary to Medicare. This questionnaire is required to be filled out by every Medicare patient who walks through the door for treatment. An RHC may see approximately 50 patients per day; over 60 percent of the population are patients who are Medicare qualified.

Also time consuming is the need to explain/reinforce that Medicare does not cover routine physicals and blood work that does not have a covered diagnosis for that test. If the patient does require blood work at the time of the visit, the doctor and nurses spend quite a bit of time looking to see if the symptoms the patient is having or diagnosis the patient has is covered for that particular test. For example, if the patient is having a pap smear, personnel needs to find out when the last pap smear was done in order to find out if the patient is eligible for a covered screening pap smear. If they are having the pap under a 2-year period, then a waiver needs to be signed by the patient or we are unable to collect payment from the patient. The same is true of a test ordered that does not have a covered diagnosis. The same process has to be evaluated for screening PSAs and various other tests.

Below are some specific examples involving Medicare's covered services and requirements to receive payments. This information was secured from employees who work on a daily basis with the regulatory requirements:

- 1) Routine nail trimmings In order for the clinic to receive reimbursement, a waiver must be filled out which requires the patient to pay for the service. Without a waiver, the facility cannot bill the patient. Numerous examples are cited where the patient was in need of the service, yet Medicare Part B Local Medical Review Policy (LMRP) basically only covers nail trimming for patients who have diabetes. Services are provided, but written off by the organization because no waivers were filled out or documentation did not support the claim. A lot of time is spent in the exam rooms explaining waiver information and obtaining signatures; a lot of work that seems unnecessary when a licensed medical practitioner feels this is the right course for treatment.
- 2) Injections. When a patient is referred to a specialist and the specialist orders a specific injection to be given monthly, patients often want the RHC to provide the injection since they're closer. However, reimbursement is at a set rate of approximately \$85 for STA, when often the injection costs \$500-\$1000/shot. Clinics may see the remaining payment in the cost report, often up to a year later or possibly not at all.
- 3) EOBs. Medicare Part A does not forward EOBs to most supplemental insurance underwriters (unlike Medicare B MediGap process). We are required to send a paper copy along with a copy of the Medicare EOB to the supplemental insurance. The EOB contains many patient claims so these EOBs have to be blocked out to submit only the information needed for that particular patient. We are finding even large MediGap underwriters, which have contracts to have automatic electronic transfers from Medicare Part A to them, are not being sent. Therefore, after these claims have aged 60-90 days, they will finally be submitted paper by our billing department.

(Submitted by Nancy A. Baerwaldt, Vice President, Advocacy, Trinity Health)

6. Recovery of Overpayments made to Medicare + Choice organizations -- Appearing in the January 25, 2002 Federal Register, Vol. 67, No. 17 is the requirement that Medicare + Choice organizations must notify CMS about an overpayment within 60 days of the receipt of that overpayment. This time frame should be increased substantially.

- 1) The CMS proposed rule requires that overpayments be returned within 60 days of the provider "identifying" or "learning" of the excess payment. We request that CMS provide a definition on the meaning of "identifying" and "learning."
- 2) The proposed rule requires that the provider "notify the carrier or intermediary, in writing, of the reason for the overpayment." We request that CMS provide a model form for this notification.
- 3) The proposed rule only deals with individual claims. But how would a provider address issues that are systemic over multiple claims (e.g., thousands of claims)? We request that CMS provide clarification.

(Submitted by Nancy A. Baerwaldt, Vice President, Advocacy, Trinity Health)

7. Revise the Medicare Secondary Payor regulations (42 CFR 411.24): Currently, hospitals must fill out a Medicare as Secondary Payor (MSP) form every time a patient comes to the hospital for a procedure. This is an unnecessary burden that is costly to the hospital in terms of staff time and resources and to beneficiaries, who must respond to the same questions every time they come to the

hospital – even if they are required to come in on a weekly or daily basis. Additionally, hospitals that serve as reference laboratories are required to track down a beneficiary whose lab specimen may have been sent there in order to determine whether the beneficiary has other insurance coverage.

Recommendation: The intent of the underlying statute (Section 1862(b)(6)(A) of the Social Security Act) can be maintained if the regulation is changed to require that hospitals collect MSP information *no more than once per 90 days for each beneficiary* requiring services and should not be responsible for MSP information for non-patients (e.g., lab referrals).

(Submitted by Steve Brennan, System Director, Advocacy & Public Policy, Providence Health System)

NOTE: On March 20, 2002, CMS Administrator Tom Scully announced that hospitals will be able to gather the MSP information every 90 days rather than every 30 days.

8. MSP Questionnaire. These questions are confusing to many of the patients and not totally accurate. For instance, it does not ask if Hospice and/or an HMO policy should be billed. Again Medicare is holding the facility responsible for this information.

(submitted by Carmela Brown, Government Relations, Mercy Medical Center, Des Moines, IA)

9. Regulations concerning oxygen and CPAP benefits. The need for a physician's prescription for every replacement CPAP accessory, i.e., masks, headgear, tubing, filters, etc. These items are necessary for the use of the prescribed equipment to interface with the patient, like a nasal cannula is needed to interface with the patient and their oxygen equipment. I think of them as prescription refills. The original physician's prescription order and CMN is for a lifetime medical need, making the need for replacement accessories also lifetime medical need.

The Region D DMERC Supplier Manual, Revised January 2001 Chapter 9, CPAP, page 1 lists the HCPCS codes for these accessories as K0183 through K0189. The same "K" codes are also referenced in Chapter 9 Respiratory Assist Device (RAD) with a table that represents the usual maximum replacement amount expected to be medically necessary. The whole Region D DMERC Chapter 9 Respiratory Assist Device (RAD) is very burdensome for all involved, from patient, physician to DME provider. It involves a great deal of intense follow up commitment and burden on the patients, their physicians and DME suppliers to insure proper benefit coverage and reimbursement.

(submitted by Carmela Brown, Government Relations, Mercy Medical Center, Des Moines, IA)

Codes and Coding Policies

1. Inconsistent Coding Guidance. Currently the American Hospital Association (AHA) Coding Clinic for ICD-9-CM serves as the official reference for coding advice, as designated by the major cooperating parties in healthcare - the American Hospital Association (AHA), American Health Information Management Association (AHIMA), Centers for Medicare and Medicaid Services (CMS), and the National Center for Health Statistics. Carriers, Fiscal Intermediaries (FI's) and CMS frequently fail to follow or reference the AHA official coding standards when providing commentary or guidance in Local Medical Review Policies (LMRPs) or Federal Register

promulgations. Further, CMS fails to enforce adherence to Coding Clinic rules among its agents – the FI's and Carriers. As a result, LMRPs and commentaries are issued that are contradictory to professional coding standards and, therefore, place coding staff and providers in the position of “choosing” which set of coding rules to follow. This is counter-productive as it creates the potential to misinterpret or misrepresent medical conditions because of regional variances in coding or terminology applications and creates potential compliance problems that could be avoided by clearer, better-coordinated guidance. While CMS may choose to delegate authority to professional associations to develop, implement and manage various critical portions of the reimbursement system, CMS cannot delegate responsibility for ensuring that Medicare providers and beneficiaries have a cohesive, consistent, and clear system that promotes clarity, comprehension and compliance.

Recommendation: CMS should develop a more collaborative guidance promulgation process, especially if it is going to defer to the expertise of AHA's Coding Clinic and the American Medical Association's CPT coding guidelines and delegate to them responsibility for critical portions of the reimbursement system for federal health care programs. The more collaborative process should ensure that all national, FI and carrier rules, policies and practices are consistent with the decisions and guidance of these national bodies. CMS should require its staff to obtain the concurrence from such experts with delegated authority to administer portions of the federal health care programs that CMS's (or the FI's or carrier's) proposed interpretation is consistent with the letter and the spirit of the expert's promulgations on the topic before issuance of each proposed or final guidance or policy from the central or regional CMS offices, or from an intermediary or carrier.”

(submitted by Donald E. Koenig, Vice President, Corporate Responsibility, Catholic Healthcare Partners; Cincinnati, OH)

2. Code discrepancies. Some guidance given by CMS in the Federal Register and in other communications, concerning assignment of diagnosis codes is inconsistent with Official ICD-9-CM Guidelines for Coding and Reporting. An example can be found in the November 30, 2001, Federal Register, on pages 59880 - 59881. A commenter had suggested that diagnosis codes for weakness, palpitations, rapid heartbeat and syncope should be added to the list of diagnoses that support coverage of observation for patients having "chest pain". The response stated, "If a patient has one of the other suggested symptoms (weakness, palpitations, rapid heartbeat, and syncope), it would be appropriate to use one of the proposed codes as the diagnosis (for example, 413.9, other and unspecified angina).

If a physician ordered observation for a patient because of rapid heartbeat and syncope, but did not note "unspecified angina" on the patient chart, it would be a clear violation of coding rules for the coder in the medical records department to enter the code of 413.9. Yet that appears to be the suggestion in the Federal Register.

Similar lack of understanding of coding rules was evidenced in a letter from the CMS Region 10 office, responding to concerns over the inappropriateness or inadequacy of the list of diagnosis codes in LMRP's that support medical necessity for services. In this specific instance, the LMRP concerned CAT scan of the abdomen, hip and pelvis. The patient had been struck by a motor vehicle while riding her bicycle. The treating physician in the emergency room ordered a pelvic CAT Scan to determine if the pain in the patient's hip was due to a fracture. Fortunately for the patient, there was no fracture. The diagnosis assigned by the physician was contusion of hip, which is ICD-9-CM code 924.01. Unfortunately for the hospital, however, that diagnosis code is not included in the

LMRP, and so Medicare refused to pay for the diagnostic procedure, even though there was no way to know in advance what the result of the scan would show. Had the hip been fractured, the scan would have been covered. Ironically, had the injury been diagnosed as contusion of buttock, code 922.32, the scan would have been covered.

After questioning why contusion of the hip was not considered a covered diagnosis for this procedure, when contusion of the buttock was, the response from region 10 stated, "The buttock is reasonably close to the hip so 922.32 may have been appropriate."

Unfortunately, coders are not allowed to be just "reasonably close". They must only code what the physician describes, not something reasonably close in order to obtain payment for the facility.

Inconsistencies in the LMRP's between states and between carriers and FI's have already been pointed out numerous times, and movement to national coding policies may help address these issues. But CMS officials, whether responding to individual letters or preparing responses for publication in Bulletins or the Federal Register, need to understand coding rules before giving advice on coding issues.

(Submitted by Michael Frith, Business Office Director, Saint Alphonsus Regional Medical Center, ID)

3. E&M guidelines, billing (excerpt from Margaret Barron testimony at January 7 Advisory Commission Hearing)

The billing guidelines are incredibly complex, especially for emergency medicine. There are five levels of service, 1 through 5, with 1 being a very simple thing -- I pinched myself and I need a tetanus shot. That's a level 1. I'm having a heart attack and I need to be admitted, level 5. Most of these things are common sense. But if you look at what you have to put down on paper, it becomes a game. In order for me to bill a level 4 visit, there is a grid. I have to have X pieces of documentation from the organ systems, and I think for a level 4 I have to have 9 of 14 organ systems covered, even though you're coming in for your heart attack. I mean, I'm going to listen to your heart and your lungs and feel your belly, and then I'm going to get going, okay? You don't want me looking in your ears. But in order for me to get up to a level 4 or 5 visit, I have to put all these things down. You know, if you're 94 years old, I'm sorry but your family history is not relevant. So there are things that you do to get to these levels of service that I have to document that, frankly, don't make any sense. You're documenting for billing, you're not documenting for patient care.

(Submitted by Dr. Margaret Barron, MD, Providence Hospital, Washington, DC)

4. Usage of Different CPT Codes for the Same Services. CMS permits inconsistencies among coding conventions that exacerbate complexity and confusion among coders. Sometimes, the different codes are related to the identity of the payer; other times to whom provides the service or performs the procedure. Examples include:

- Current software available to support hospital billing efforts has limited capability in providing alternative coding options. Most vendors restrict alternative coding to a financial class level (e.g., Medicare, Medicaid, Managed Care) rather than at the specific insurance plan level. It is at the plan level within Managed Care that most contractual variances in coverage and coding occur.

Example: Partial Hospitalization Psychiatric services is a covered benefit under the Medicare/Medicaid programs. A vital component of Partial Hospitalization is activity therapy services. Activity therapy services have been historically a source of fraudulent practices. However Medicare and Medicaid have eliminated some of issues by creating a new HCPC II code and a clear definition of activity therapy. Providers and auditors now have a means to define, identify, and audit services falling under the classification of "activity therapy." Managed Care plans however have not been supportive of the new definition of "activity therapy" as defined by Medicare/Medicaid and have historically not supported the use of national HCPC II coding. Instead, Managed Care has requested providers to "re-classify" activity therapy patients into other existing CPT-codeable services (e.g., group therapy or individual therapy) or to create "home-grown" coding that corresponds to no official coding nomenclature. This practice establishes historic records that do not properly reflect the clinical services performed which can have far reaching impact on future rate setting, clinical profiling, and trending of healthcare services in general.

- Coding of wound debridement services differs between physicians and hospitals. When provided by the physician, CPT coding in the 11000's series is required. When provided within the hospital setting and by non-physician personnel, the CPT codes 97601 versus 97602 are required depending on if the debridement is "selective" or "non-selective". As a result, a two-tiered coding methodology is created for the same medical procedure.

Recommendation: Procedural codes should be unique to the procedure, and consistent regardless of the payer, provider, or site of service. CMS must represent more aggressively the interests of providers and beneficiaries with delegated coding authorities to ensure a cohesive, clear system."

(submitted by Donald E. Koenig, Vice President, Corporate Responsibility, Catholic Healthcare Partners; Cincinnati, OH)

5. Usage of different CPT codes for different payers. Medicare uses one CPT code, Medicaid another, John Deere another. Development and usage of standard codes for all payers. Also their units with these CPT codes (example: Diabetes 30 Vs 60 minutes or wanting each for some types of service and whole program for others).

(submitted by Carmela Brown, Government Relations, Mercy Medical Center, Des Moines, IA)

ERISA and Nurse Shortages

Bona Fide Retirees and the Nursing Shortage. -- A significant barrier to our being able to partially ameliorate the health professionals' shortage is our inability to "hire back" relatively soon after retirement our retired registered nurses and other health professionals.

The barrier is the regulatory language promulgated pursuant to the Employee Retirement Income Security Act (ERISA). The regulations direct that for a pension fund to maintain its tax-exempt status, the monies drawn by individuals from the fund must be to those whose separations from the employer are bona fide.

The ERISA regulations governing such separations do not define how much time must

elapse between the date of retirement and the date the retiree returns to work for the same employer for a separation to be bona fide. However, it is assumed by attorneys versed in ERISA and pension law that there must be a significant time lapse between the date of retirement and the date of re-employment (with continued receipt of pension payments by the "re-employed retiree") by the employer from which the employee separated.

Put specifically, attorneys hesitate to interpret as a bona fide separation a retirement in which the "retiree" returns to work with the same employer, with full pension benefits, 120 days following the retirement.

It is to state the obvious to note that recently retired health care professionals are some of our most valuable potential employees. While these newly retired health care professionals are often free to "go down the street" to work for another health care facility and continue to draw full pension benefits from the facility from which they retired, they are most valuable to the health care facility from which they recently retired. Additionally, for some recently-retired individuals, who may wish to return to work at our facilities, there may not be the "go down the street" option.

The Potential Solution For Health Care Providers: Health care facilities need: (1) clarification of the minimum number of days after retirement and before re-employment with the same employer in which the separation can be considered bona fide; and (2) a relatively-short (e.g., 120) minimum number of days for the separation to be considered bona fide in the case of retired health professionals.

(Submitted by Nancy A. Baerwaldt, Vice President, Advocacy, Trinity Health)

HIPAA --Health Insurance Portability and Accountability Act

1. De-identification -- We have appreciated the care the Department of Health and Human Services has shown in the promulgation of the privacy portion of the HIPAA regulations. We would like, however, to call to your attention the "de-identification" requirements for hospital data used for clinical and other research purposes, an element of the regulations we believe still needs attention.

Trinity Health hospitals, like just about all hospitals, rely on the availability of comparative hospital data to ascertain quality improvement opportunities and determine market trends. Both sets of information are vital to our being able to effectively serve our communities and patients. As such, we are particularly concerned about the standards and implementation specifications for the "de-identification of protected health information" used for research purposes. These requirements are enumerated in §164.514 of the HIPAA privacy regulations.

The severe limitation on the use of the 4th and 5th digits of a zip code (§164.514[b][2][I][B] – "if 20,000 or fewer people {must} be changed to 000") is particularly troublesome. This limitation is a significant barrier to our being able to conduct quantitative research on medical care and marketplace trends. Specifically, in order for us to compile comparative statistical information about the quality of care (mortality, morbidity, etc.) and trends in market penetration, we need to access data that has all five digits of the zip code, even when there are "20,000 or fewer people" resident in the geographic area that comprises the five digits of the zip code. We therefore recommend that zip

code be entirely eliminated from the "de-identification" requirements so that the complete zip code is able to be utilized for research and market analysis.

Additionally, the protocol requiring that "[a]ll elements of dates (except year)" be "de-identified" (§ 164.514[b][2][I][C]) is also too severe for the data comparisons we need to make. It is to state the obvious to note that for certain diagnoses, there is seasonality in admissions and discharges. Understanding this seasonality, and trends in same, gives us the opportunity to appropriately accommodate patients. We therefore recommend that the "admission date, discharge date" be removed from the de-identifiers so that they may be utilized for research and market analysis.

(Submitted by Nancy A. Baerwaldt, Vice President, Advocacy, Trinity Health)

2. Cost and Complexity of Complying with HIPAA. Protecting the privacy and security of sensitive health care information is critically important to our health system, our 35,000 associates, our 8,000 affiliated physicians and our hundreds of thousands of patients, residents and their families. But the new HIPAA privacy rule places a tremendous financial burden upon hospitals and providers. This is particularly important regarding our hospitals that are heavily reimbursed by public programs. The government itself estimates the total cost to be nearly \$18 billion over five years. Other studies suggest the price tag is more than \$22 billion for hospitals alone, and that those costs will not be offset by efficiencies brought by HIPAA's electronic transaction requirements.

Much of the extensive costs of complying with the HIPAA privacy provisions were offset in federal calculations (including calculations of its compliance with the Un-funded Federal Mandates Act -- UFMA) by the promise that hospitals and other providers would reap significant savings from the implementation of the standardized transaction and code sets prior to implementation of the privacy rules and that the significant privacy and security upgrades necessary could be funded from those savings. In late 2001, Congress reversed the order of compliance by delaying the effective date of the transactions and code sets until October 16, 2003, some six months after full compliance with the privacy rules must be achieved.

Recommend that CMS undertake new calculations of the cost of compliance with the privacy provisions of HIPAA, once the final HIPAA privacy provisions are approved, reassess whether the rule complies with the UFMA in light of the change in compliance order, and make appropriate regulatory recommendations to assist providers in achieving timely, cost-effective compliance."

(Submitted by Sr. Marjorie Bosse, Vice President, Catholic Healthcare Partners, Cincinnati, OH and Donald E. Koenig, Vice President, Corporate Responsibility, Catholic Healthcare Partners)

3. Coordination of HIPAA compliance dates. In order to comply with the letter and spirit of the HIPAA legislation, CMS should extend the compliance date for all components of HIPAA (privacy, security, transaction and code sets, identifiers) until 26 months after the promulgation date of the final HIPAA regulation. Because of the inter-related nature of privacy and security enhancements, policies and extensive training, it is impossible and inexorably expensive for providers to attempt to do this in a piecemeal fashion. Information privacy and security is far too important to be accomplished in such a slapdash fashion.

Secondly, the fact that the "final" privacy regulations have been "tweaked", "clarified" and "amended" three times so far by the Bush administration, and are not yet *really* final would seem to

require that the privacy regulation compliance date be re-set by CMS to be 26 months from when the final regulations are promulgated (expected sometime this summer.) Congress mandated in HIPAA that providers are to have 26 months to come into full compliance with the final regulations. We agree wholeheartedly that the changes and clarifications have been needed, and we appreciate them, but continual regulatory changes without adjusting the April 14, 2003 compliance deadline makes it impossible for providers to implement thoughtful, effective training in the limited time remaining, and appears to violate the clear Congressional mandate that providers have a full 26 months to come into compliance.

We recommend that CMS change the HIPAA privacy compliance date to 26 months from when CMS issues the final HIPAA Privacy rule and we recommend that CMS harmonize all HIPAA final compliance dates to be 26 months from when the final HIPAA regulation is promulgated.

(submitted by Donald E. Koenig, Vice President, Corporate Responsibility, Catholic Healthcare Partners; Cincinnati, OH)

4. CMS determination of HIPAA Pre-emption Status. Given the extraordinary cost (quoted in excess of \$100K per state) and complexity of state analyses of pre-emption of HIPAA, some providers are awaiting pre-emption analyses from state medical societies or state hospital associations; others just assume that assistance will come eventually.

Recommendation: CMS should agree to provide a definitive pre-emption analysis for all 50 states to ensure that all providers in any state address critical patient information privacy and security in a consistent fashion. Only the federal government has at its disposal the extensive legal resources necessary to undertake such analyses and produce them in a consistent format.

(submitted by Donald E. Koenig, Vice President, Corporate Responsibility, Catholic Healthcare Partners; Cincinnati, OH)

Appendix

CHA-Member Contact Information

Recommendations submitted from the following CHA member Systems and facilities are included in this compilation:

B

Christopher M. Carney

CEO/President

Bon Secours Health System, Inc.

1505 Marriottsville Rd.

Marriottsville, MD 21104-1399

410-442-5511

Also from **Bon Secours Health System:**

Keith Braganza, Director of Budget

410-442-3217

Keith_Braganza@BSHSI.com

Sherry Brunner, Vice President for Risk Management and Loss Prevention

410-442-3200

Sherry_Brunner@BSHSI.com

Maggie Costella, Director of Legal Affairs

410-442-3316

Margaret_Costella@BSHSI.com

Joeann Karibo, Director, Community Commitment

410-442-3203

Joeann_Karibo@BSHSI.com

C

Carmela Brown

Government Relations

Mercy Medical Center

Catholic Health Initiatives

1111 6th Ave.

Des Moines, IA 50314-2611

515-247-4283

mrccmb@aol.com

Sr. Marjorie Bosse, RSM
Vice President, Advocacy/Community Service
Catholic Healthcare Partners
615 Elsinore Place
Cincinnati, OH 45202
513-639-2827
mmbosse@health-partners.org

Also from **Catholic Healthcare Partners**:

Donald E. Koenig, Jr.
Vice President, Corporate Responsibility
Catholic Healthcare Partners
615 Elsinore Place
Cincinnati, OH 45202-1459
513-639-2833
dkoenig@health-partners.org

Shelly Schlenker
Catholic Healthcare West
% Rachelle R. Wenger
Manager, Public Policy & Advocacy
Catholic Healthcare West
251 South Lake Avenue
Pasadena, CA 91101
626/744-2209 phone
626/395-0499 fax
rwenger@chw.edu

P
Steve Brennan
System Director, Advocacy & Public Policy
Providence Health System
506- 2nd Avenue, Suite 1200
Seattle, WA 98104-2329
206-464-4717
sbrennan@providence.org

S
Michael Frith
Business Office Director
Saint Alphonsus Regional Medical Center
1055 N. Curtis Rd.
Boise, ID 83706-1370
208-367-2145

Dr. Jabbar Fazeli, MD

Sisters of Charity Health System, Inc.

PO Box 7291

Lewiston, ME 04243-7291

207-755-3360

T

Nancy A. Baerwaldt

Vice President, Advocacy

Trinity Health

27870 Cabot Drive

Novi, MI 48377-2920

248-489-6774

baerwaln@trinity-health.org

Also from **Trinity Health**:

Bill Anderson, Senior Vice President, Human Resources

Bruce Van Cleave, M.D., Executive Vice President, Clinical and Physician Services

Diane Arsenault, Assistant General Counsel

Scott Curtis, Administrator, Kossuth Regional Hospital, Kossuth, Iowa

Many thanks to our reviewers:

We particularly want to thank those who agreed to serve as reviewers for this project, including: Nancy Baerwaldt and her colleagues from Trinity Health; Sr. Marjorie Bosse, RSM and Don Koenig from Catholic Healthcare Partners; Steve Brennan from Providence Health System; Carmela Brown and her colleagues from Catholic Health Initiatives; Joann Karibo and her colleagues from Bon Secours Health System, Inc.; and Shelly Schlenker and her colleagues from Catholic Health Care West.