Statement of Nicholas J. Wolter, MD, CEO
Deaconess Billings Clinic

May 28, 2002

Senate Finance Committee Field Hearing
on

"Regulatory Relief for Medicare – the Case for Cutting Red Tape"

Chairman Baucus, I appreciate this opportunity to discuss some of the challenges that physicians and health care organizations face in the ever growing and complex arena of government rules and regulations.

I am submitting these comments on behalf of Deaconess Billings Clinic. DBC is a not-for-profit, physician-led, community governed medical foundation serving Montana and northern Wyoming. It is composed of 170 physicians, located at 10 clinic sites, as well as a 272 bed hospital, a nursing home, and a research division. DBC also manages several small hospitals and nursing home facilities in towns with populations of less than 10,000.

DBC, like many other large health care organizations in rural states, serves a very large geographic region with primary, secondary and tertiary care services. It is common for patients to travel 90 minutes to Billings for a primary care visit, and five hours or more for a visit to one of our medical subspecialists. As part of a consortium of rural hospitals, DBC also operates a telemedicine network. DBC's mission is to improve the health of the communities we serve, and to support health care research and education.

I am Dr. Nick Wolter, the CEO of Deaconess Billings Clinic. I have spent most of my professional life practicing critical care medicine and pulmonology, and I still see patients today.

I'd like to start with several simple premises.

- Medicare should support the physician-patient relationship.
- Medicare should encourage quality, coordinated, and efficient care.
- Medicare regulations should be as simple and inexpensive to implement as possible.
- Medicare regulators should work in a cooperative, partnership manner with physicians and other providers.

Deaconess Billings Clinic believes that operating from these premises can provide Medicare beneficiaries, our patients, with the best care and the best value.

Better Guidance, More Coordination, and More Oversight from the National Level is Needed

Documentation, Billing, and Coding Guidelines

Physicians, hospitals, and other health care organizations face an enormous paperwork burden created by many regulations promulgated by the Centers for Medicare and Medicaid (CMS) and the Department of Health and Human Services. Much of this paperwork is unnecessary to the intended outcome and results in a waste of valuable resources that would be better spent on providing care and dealing with pressing new issues like the threat of bio-terrorism. Further, many of the regulations appear to be unnecessary and intrusive into the physician-patient relationship and many impose costs and burdens on health care organizations that far outweigh any benefit.

Example: Preventive Medicine Codes

Every day, patients, especially in our internal medicine practices, are confused by how they are charged for preventive care because of unclear and contradictory coding guidance from CMS and our local Medicare contractor on a preventive medical exam, versus a problem medical exam. Medicare does not generally pay for a preventive exam, the patient does. So this is an area of great patient interest, where clarity is important. Furthermore, preventive exams are common. Therefore, you would think that the guidance would be clear by now. What we find, however is the following:

- It is very difficult to determine, under current guidance, when a preventive medical exam becomes a problem exam.
- It is also very difficult to determine when a preventive exam becomes *both* a preventive exam *and* a problem exam, during the course of an exam. For instance, if the physician finds a potential heart problem or diabetes, when can billing be done for treatment beyond what would be done in the routine preventive exam? In this instance, we are faced with figuring out the correct billing procedure and making sure we do not charge the Medicare beneficiary for the part of the exam that should be billed to Medicare. This situation is extremely difficult to explain to the patient, even if we could get clear guidance from Medicare.
- Medicare now allows certain preventive tests for women (e.g. a screening pap smear, a breast exam and a pelvic) to be performed and billed to Medicare at the same time as a problem visit billed to Medicare. This is not the case in regards to screening for men. We may bill a preventive screening digital rectal exam to Medicare, but not at the same time as a problem visit billed to Medicare. This is difficult to understand and more difficult to explain to the patient.
- To make this issue even more confusing, we have been faced with differing interpretations from our Carrier and the Medical Director of our Carrier, as well as the Medicare Regional Office on these questions. There are no clear national guidelines in this area and this only perpetuates the confusion.

DBC recommends that this problem be solved by allowing covered preventive tests to be billed during any type of visit, as long as medically appropriate time frames are followed.

Example: Documentation of Patient Status: Inpatient, Outpatient, and Observation

Currently, the Medicare PRO in Montana has advised us that the initial documentation of patient status as an inpatient, outpatient, or observation patient controls for billing purposes, and may not be changed, even in the face of better information. The PRO claims it is following national guidance.

A good example is when an emergency physician admits a patient as an "inpatient," then the hospitalist, upon further evaluation, determines that the patient should be held for "observation" instead. Currently, the hospital would not be allowed to change the patient's status prior to billing, and, if it is determined that the patient did not meet inpatient criteria, nothing can be billed. Often, for complex patients, several physicians are involved in care. The case managers or UR nurses need time to review documentation, request clarification from physicians as needed, and determine appropriate status. The current process, which does not allow this, is punitive.

Physicians should be able to change documentation to reflect better information about patient status as warranted during hospitalization and prior to billing of services (e.g., 48-72 hours post discharge) for the purpose of clarifying patient status.

Medicare Carrier Review Processes Must be Improved

Medicare has often taken a punitive, rather than an educational, approach to complex coding issues. One area of special concern has been efforts to collect so-called overpayments from physicians. For instance, extrapolation of overpayments made to physicians based on probe samples is unfair and inaccurate. Physicians and carriers must be able to take steps to rectify coding issues before formalizing an overpayment request, and such requests should be based on actual claims reviewed, not on extrapolation. CMS should ensure that repayment options for overpayments are practical and should provide adequate due process protections. Finally, CMS should ensure that physicians are appropriately educated about Medicare requirements and should act as the channel for communication between physicians and carriers.

We urge you to include language in S. 1738, the "Medicare Appeals, Regulatory, and Contracting Improvement Act of 2001" (MARCIA).

- Appropriately limit the use of extrapolation: When conducting post-payment audits, carriers should be able to use extrapolation only where there is either a sustained or high payment error rate, or the carrier's documented education efforts have failed.
- Appeals Rights: Physicians should be able to appeal administratively the probe sample findings that carriers use during post-payment audits. Physicians should not be forced to undergo a more intensive audit just to maintain their appeal rights, but should have the right to appeal the probe sample audit itself.
- E&M Pilot Projects: Require CMS to conduct pilot tests of any new E&M documentation requirements before implementation on a nationwide basis. Physician organizations would have to be involved in the pilot project design, implementation and analysis.

Teleradiology

Medicare regulations should not inhibit expansion of teleradiology by organizations like DBC, using radiologist support from out-of-state sites to support local efforts by radiologists. As a clinical matter, the location of radiologists is irrelevant, given existing technology. DBC has built a secure, computer-based imaging network to address the crying need for radiology services in Montana. Small communities often can't support a radiologist, and certainly can't support subspecialty radiology expertise that is increasingly medically important. The technology exists to provide these services to underserved rural beneficiaries (and the physicians in those communities), but Medicare rules make it difficult to bill Medicare in Montana for the services of contracted radiologists. CMS should evaluate Medicare billing rules, as applied nationally, to encourage the rapid adoption of new teleradiology technology.

Local Medical Review Policies ("LMRPs"), "Medical Necessity" Determinations, and other Guidance (or lack thereof)

Medicare requires local Medicare contractors to decide what is medically appropriate care, within the context of national guidelines. The number of LMRPs varies enormously across the country by Medicare contractor, and the advice is often inconsistent. The effect is that beneficiary services vary from area to area because of the variations within Medicare administration. Quality may also be inconsistent. Medical evidence should drive Medicare's medical review policies, not variability in the opinions of local Medicare Medical Directors.

Nothing is more difficult for a practicing physician than to be told by the local Medicare contractor that the service he is providing or has authorized is not "medically necessary," especially when that payment denial decision is not supported by current medical evidence, is inconsistent with accepted practice, and threatens patient care.

Example: Air Ambulance

Let me give you one recent, extremely serious example in Montana right now, involving air ambulance services. DBC, like several other hospitals in the state that provide trauma and higher level medical services, owns and staffs an air ambulance. The medical director of that service refers to it as a "flying ICU." We can and do save lives because of air transport, especially in a rural state, where many of the health care facilities in smaller communities are not able to care for complex cardiac patients or serious trauma. However, since January 2000, our local Medicare Fiscal Intermediary has downgraded approximately thirty-nine (39%) of our air transports to land ambulance, claiming that air transport was not necessary. We understand similar denials are not common with Medicare FIs in other states. This has involved hundreds of thousands, if not millions, of dollars of losses to air ambulance providers, both in denied payments and in the operational costs of appealing hundreds of claims. These losses could threaten the long-term availability of air transport in some parts of Montana. For that reason, we have been fighting hard to assure services.

Let me give you two examples of downgrades that illustrate the seriousness of the threat to patient well-being posed by our local Medicare Fiscal Intermediary's extremely narrow view of when air transport is medically necessary:

- A 78 year old female sustained a huge intracerebral hemorrhage and was transported by air for neurological evaluation. Vital signs were stable enroute and the patient was confused with slurred speech. Upon neurological evaluation, it was determined by the neurologist that the patient would likely not survive the event. The family made decisions for comfort care and the patient passed away 4 days later. This flight was denied by Medicare, stating that the patient was stable and could have been transported via ground ambulance. Due to the extent of her intracerebral hemorrhage, she could have compromised her airway at any time and did in fact lose consciousness shortly after arriving at DBC. We have appealed this denial.

- A 68 year old male presented to the Emergency Department of a small hospital with chest pain. The patient had an abnormal EKG and elevated cardiac enzymes indicating that he had suffered a heart attack. He was stabilized and transported by air for cardiac evaluation, and was not in active pain during the transport. The admitting cardiologist decided that due to the recent myocardial infarction, it was best to perform cardiac catheterization the following morning. The patient underwent cardiac catheterization within 18 hours of transport and underwent multiple vessel coronary artery bypass later in his hospital stay. This transport was denied based upon the fact that the patient was stable during the transport. The FI stated that the patient must experience chest pain during the transport to establish the medical necessity of air transport. We are appealing this denial based upon the fact that you can never predict which patients will be stabilized and which will continue to evolve and extend their myocardial infarction.

Basically, the medical judgement of the physician responsible for a patient's care at the hospital that initiates air transport has been reversed by a person in the Medical Review department of the local Medicare Fiscal Intermediary looking at a paper record, apparently with an eye toward finding a reason to deny. In our experience, the local Medicare Medical Review department has consistently made decisions that, we believe as physicians, seriously threatens patients. For that reason, we have appealed a very high percentage of the air ambulance downgrades by our local Medicare Fiscal Intermediary. While appeals are expensive, we have also had a very high rate of initial downgrades overturned, so far. Unfortunately, while the rate of downgrades has lessened since January of this year, DBC is still experiencing an initial rate of downgrades of air ambulance to land of approximately 28%.

Senator Baucus, We appreciate your support and understanding on this issue, and understand that you intend to introduce legislation that would address our problems. Such legislation will save lives in rural communities in Montana. Thank you.

<u>Improve the Performance of the Fiscal Intermediaries and Carriers</u>

DBC supports the need to restructure Medicare contractors, with a primary objective of providing better service to providers, physicians, and other health care professionals. We believe this will require that providers and physicians have direct access to better information resources, either

through the FIs and Carriers, or directly through more adequate guidance from Medicare nationally. At the same time, any Medicare contractor for Montana must be well versed in how services are delivered in a very rural and large state. As you can tell from the previous discussion, it is frustrating, time-consuming and expensive for DBC to work within the current structure of Medicare contractors and regulations. Because of the volume and complexity of our claims, and because of our commitment to an effective compliance program, we often identify claims issues involving the Medicare contractors sooner than other providers in the state. Often our FI/Carrier lacks the internal resources to answer our questions in a timely manner. It also does not have a technology specialist on staff who can answer basic questions about electronic submission of claims or who can fix problems with their computer system. In our experience, any solution to the problems we have with Medicare, and specifically with our Medicare contractors, requires more resources.

We urge the inclusion in S. 1738 of contractor performance review utilizing results of monitoring the accuracy, consistency, and timeliness of information as obtained through consultation with provider organizations who help develop the standards.

Ineffectiveness of Dispute Resolution with Medicare

Physicians, hospitals and other health care providers need help getting our disputes with Medicare resolved in a more timely and cost-effective manner. We believe this requires reform at two levels.

First, as is the case with air ambulance, we expect to have hundred of claims in appeal. Many of them involve essentially the same material facts and the same question of medical necessity. We are confident that we will win on appeal before the administrative law judges, for those cases we aren't able to get reversed before that in the appeals process within the Medicare Fiscal Intermediary. But even if we win dozens of appeals before the ALJ, all involving the same issues, there is no way currently to force the Medicare Fiscal Intermediary to change its policies. It can continue to deny and downgrade claims without regard to success by providers in appealing those claims.

We have discussed this issue with you and your staff on the Senate Finance Committee, and understand that you intend to introduce legislation that gives providers avenues for making Medicare contractors change their policies in such situations. This involves both an amendment to Sec. 522 of BIPA to give providers standing under appeals reform initiated by Congress earlier, and a new provision that would allow providers to petition the Secretary to direct a Medicare contractor to make or revise local policies, taking into account actual success in front of ALJs. We appreciate your understanding on this issue.

Second, at this point, providers have no way to challenge the legality of regulations and conduct by the Department of Health and Human Services on an expedited basis. This is true even if the regulations and conduct are unconstitutional or violate the underlying statute enacted by Congress or the Administrative Procedures Act. It should be possible to challenge such regulations and conduct as soon as they occur, before they are implemented, on an expedited basis. However, under US Supreme Court precedent in Shalala v. Illinois Council on Long Term Care, a provider

is only able to challenge a regulation through an administrative process that requires that the provider first violate the regulation, in order to get standing to challenge it. Since penalties for violating Medicare regulations can include exclusion from the Medicare program, this puts providers in an untenable position.

Congress should revise Medicare law so that when providers dispute the legality of HHS' regulations or actions, they are entitled to bring an action in court, on an expedited basis, without having to first violate the regulation.. We would encourage inclusion of this provision in S. 1738.

Medicare Rules often Micromanage Care and Direct Physicians How to Practice Medicine and Impose Onerous Paperwork Requirements

A few examples should suffice to demonstrate the problem with overly prescriptive regulations that interfere in the physician-patient relationship:

The "Inpatient Only" Designation

Designation of "Inpatient Only" services was part of the Medicare Hospital OPPS rule, published April 7, 2000. The Inpatient Only procedure list attempts to replace clinical judgment with government regulation. The rule that Inpatient Only procedures will not be paid if performed on an outpatient basis conflicts with CMS requirement that patien's be admitted as inpatients only if they meet clinical criteria. Admitting patients as inpatients to comply with the Inpatient Only procedure list may well result in hospitals admitting patients who do not meet clinical inpatient criteria. This puts the hospital at risk for have services denied for payment. It also may make an inpatient bed unavailable to a patient who really needs it.

The dictates of the Inpatient Only procedure list also conflict with many commercial insurance guidelines for what procedures should be performed on an outpatient basis. Hospitals are forced to base medical decisions on payment source rather than clinical needs. Conflicting standards are cumbersome for hospital registration, case management, nursing and coding staff.

The Inpatient Only procedure list is often obsolete. A list based on historical data, often several years old, cannot keep pace with the innovations in health care technology and delivery. Hospitals are penalized financially for advances in medical care that allow them to provide services in a more efficient and cost effective setting

The financial burdens of the Inpatient Only procedure list affect the Medicare trust fund, patients and hospitals. Since inpatient DRG reimbursement is generally higher than a corresponding outpatient APC payment, it costs the trust fund more if procedures safely performed on an outpatient basis must be performed on an inpatient basis. Patients may be financially burdened if the inpatient deductible is higher than the corresponding outpatient procedure co-payment would be. Potentially, the patient may bear complete financial responsibility for an outpatient hospitalization if he/she knowingly chooses to have an inpatient only procedure done on an outpatient basis.

Proposed solutions:

- Eliminate the Inpatient Only list and allow clinical criteria, standards of medical care, and risk of legal liability to determine the appropriate level of service.
- Allow hospitals to appeal Inpatient Only denials through Quality Improvement Organization or Fiscal Intermediary medical review channels. Medical Review findings could determine reimbursement for the case being reviewed and be used to improve timeliness of updates to the inpatient only list.

Physician Supervision of Diagnostic Tests (Program Memorandum Transmittal B-01-28, issued April 19, 2001)

This rule tells physicians, mainly radiologists, 1) when they must "generally supervise" a procedure, which means the procedure is furnished under the physician's direction and control, but their physician presence is not required, 2) when they must "directly supervise, which means they "must be present in the office suite and immediately available," but not in the room, or 3) when they must "personally supervise," which means they must be in the room during the performance of the procedure. The supervision requirement has meant that patients requiring contrasts for MRI must be done under direct supervision of a physician. As a result, patients requiring that procedure frequently must wait for the procedure, sometimes for hours, sometimes for days, raising quality of care concerns. We looked at 10 years of data, and could find no evidence of any safety concerns for patients related to use of contrasts that could not be handled by the highly trained RNs and other staff present, with supervision by radiologists via highly sophisticated technology, that effectively put the physician in the room.

One-hour Rule for Review of Seclusion and Restraints in Psychiatric Facility

The Medicare Conditions of Participation, published in the Federal Register in August 2000, require physicians to physically see an inpatient who is placed under restraints or seclusion within one-hour. This rule has posed a significant operations problem for our inpatient Psychiatric Center in terms of staffing and psychiatrist burn-out, and it does not improve patient care. While proper oversight of restraints and seclusion is important, this level of micromanagement is not. This rule has had deleterious effects on DBC's ability to retain psychiatrists in the acute, inpatient setting. This is especially challenging, given our critical role in the safety net for mental health services.

The one-hour requirement for needs to be deleted or changed to allow for more realistic and flexible management of the use of seclusion and restraint.

We question the need for medical micromanagement of medical judgement through Medicare regulations and the Conditions of Participation. When it occurs, it should be based upon sound medical advice and evidence, not upon individual instances where additional safeguards were needed to prevent a bad outcome.

Advanced Beneficiary Notices

The ABN regulations impose burden on physicians/providers that impede the delivery of care to patients. If physicians followed the encouragement of government to obtain ABNs, physicians are burdened with explaining Medicare regulations about coverage to their patients. Physicians/or representative are encouraged to present an ABN when there is a likelihood that Medicare may not pay for a particular service. In order to present the ABN when appropriate, physicians/representatives need to know or have an efficient way to know which tests or services are considered to be Limited Coverage Tests/services—which is variable among Medicare Carriers and Fiscal Intermediaries. Physicians need to know or be able to access a list of ICD-9 codes to see if the patient's diagnosis codes are on the "list " of codes that Medicare will pay for testing. If the patient's diagnosis code is not on the covered list--- then an ABN needs to be presented. Why, if not required, would a physician with a busy practice take time to explain Medicare regulations? Many times, the result is that an ABN is not executed.

The ABN regulations target the wrong group**.** In the case of a laboratory test, in order for the laboratory to bill for Limited Coverage tests---the laboratory needs to submit a claim with a "payable code" or indication of a signed/properly executed ABN. Many times the patient is never at the laboratory that performs the test(s). And yet, the liability and responsibility to execute an ABN rests with the laboratory. The clinical laboratories are set up for failure.

Solutions: Either eliminate the ABN requirements for lab procedures or make it feasible for labs to comply. Even a partial elimination of the ABN requirement for frequent and relatively low cost services and procedures would be helpful.

Medicare Secondary Payor Rules

The Medicare Secondary Payment rules, which received substantial attention during the last Congress, continue to be a significant problem. This rule requires providers to ask 25 questions of Medicare beneficiaries about other payment sources. Initially, this rule required that providers gather this information on every encounter. At DBC, patients will frequently have several encounters in a day. The paperwork burden to DBC and patients, alike, was huge, and actually interfered in the process of care. At this point, our FI requires that we collect such information every two months, which is still too frequent. We understand that other FIs still require an MSP questionaire be filled out on every encounter. More reform and more centralized guidance is needed.

Stark Self-Referral Rules (42 CFR 350 et seq., authorized under 42 U.S.C. 1395nn et seq.)

There are thousands of ways to engage in beneficial activity that violates the Stark laws and triggers punitive penalties. Regulatory reform could ameliorate some of the harsh consequences.

Under the Stark laws, any "compensation" between a physician and an entity must fall within one of the statutory or regulatory exceptions, or the entity is prohibited from billing certain federal

payors for "designated health services." It is a strict liability law -- actual harm, actual intent don't matter. Failure to meet every element of one of the exceptions carries potentially terrible consequences for the ability to provide health care, especially in rural communities, even if the failure is technical and harmless and the actions by the physician and entity are beneficial.

For instance, if a physician, who is not an employee of a small rural hospital, agrees to train hospital staff on a simple outpatient procedure that is going to be added to the services of the hospital, and is paid $100 to do that training, under the Stark regulations, unless he has a written contract with that facility, both he and the facility have violated the law. As a result, the hospital would be precluded from billing Medicare for services that physician refers to that facility (for a period of time unspecified in the statute or rules), and, if that hospital provided and billed for services, it would be required to return any money it received once it discovered the technical Stark violation. This would be true even if the $100 payment met all of the requirements of the fair market value exception to Stark, except the requirement of a written agreement, and all of the patients who got the procedures at the hospital needed them, and the physician and hospital were making a special effort to bring the procedure closer to home so people would not have to travel to distant hospitals. If this physician is the only physician who provides certain services in a community with a sole community provider hospital, the physician might not be able to continue to practice in the community because the hospital could not afford not to bill for the designated health services he refers to the hospital.

Although fundamental statutory reform of the Stark law is needed, the problem described above could be partially addressed through regulatory reform that removes the requirement of a written contract from the fair market value and personal service arrangements exceptions to the Stark law. The regulations should specify a very short time frame (e.g. no more than one month) during which services could not be billed to government payors as the result of a Stark violation, especially for an honest mistake or when there is no evidence of inappropriate referrals.

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

Based on expert outside consultation using a conservative approach DBC expects to spend three million dollars over the next few years complying with Health Insurance Portability and Accountability Act of 1996 (HIPAA) rules. We support the intent of many of these rules but hope that simplification of the requirements is yet possible, and that recognition of the practical and financial implications of implementation will be taken into consideration.

We are pleased that HHS' proposal to improve the consent process by replacing the current redundant written consent requirement with written acknowledgment. The proposal for written acknowledgement greatly improves the consent process for both patients and providers. It eliminates the barriers to care created by the previous requirement while retaining strong patient protections for non-routine uses of information. Montana has already adopted one of the most stringent laws in the country on protection of health information, which DBC believes in and complies with. It doesn't require prior written consent, and yet, we simply have not seen in Montana the kinds of abuses of health information that have been a problem in other states. Our experience in Montana suggests that prior consent is not needed to fully protect patients. Requiring prior written consent in a state of vast spaces, where providers need to work together

over telemedicine and telephone, could actually impair care, in addition to creating an unnecessary and expensive paperwork burden.

The Volume and Combined Impact of the Rules is Overwhelming

As the examples above illustrate, physicians, hospitals and nursing homes are drowning in a sea of government rules and regulations. Caregivers, driven by complex rules and regulations in the Medicare program, are forced to shift their focus from patient care to "crossing the t's and dotting the i's" of paperwork. In a study for AHA, PricewaterhouseCoopers found that physicians, nurses and other hospital staff spend on average at least 30 minutes on paperwork for every hour of patient care provided to a typical Medicare patient. In the emergency department, every hour of patient care generates an hour of paperwork – including complying with the vast array of federal, state and local health regulations. And, at a time when we face serious workforce shortages, many caregivers cite regulatory burden as among the downsides of their jobs.

The impact to DBC of the financial and human resource cost of responding to many of these regulations is becoming clearer to us at DBC and is huge. Staff salaries to support physician coding total $500,000 alone. We expect to spend $3 million dollars over the next several years on implementing HIPAA regulations.

Steps are need to reduce the impact of poorly conceived, unnecessarily burdensome, and poorly implemented regulations on physicians, hospitals, and other health care providers. We suggest the following:

Coordinate the orderly release of federal regulations to allow for more seamless compliance

- Government agencies need to release regulations in a coordinated manner so that implementation does not overwhelm health care personnel and systems. That means establishing a point of accountability to coordinate regulatory activity across major federal agencies, as well as within HHS. Secretary Thompson has ordered a top-down review of all HHS regulations to determine whether they are confusing, conflicting, impose unnecessary costs or penalties or are simply burdensome. In addition, HR. 3391 and S. 1738 include language requiring consultation between HHS and the Office Management and Budget to establish an orderly timeline for the publication of final rules.

Provide interpretive and advisory guidance on Medicare payment requirements

- Medicare requirements for provider participation and payment are increasingly voluminous and complex, making compliance difficult, while penalties for noncompliance are increasingly severe. CMS should establish query mechanisms for individual providers and their associations on the appropriate interpretation or application of Medicare rules in specific situations. CMS' responses should be timely and readily available to others in an easily accessible format (such as an indexed file on the Internet). We urge inclusion of this provision in S. 1738.

Consult caregivers on rule development

- Early in the drafting process, regulatory agencies should consult those affected by a regulation – the caregivers – so practical implementation issues and problems can be identified and resolved before a particular regulatory approach is locked in. We support Secretary Thompson's recommendation that CMS pilot test new regulatory measures for workability before requiring them of providers nationwide.

The Congressional years of 2001 and 2002 have seen a flurry of activity in the area of regulatory reform, and increased Congressional attention to addressing recognized problems. The Department of Health and Human Services and the Center for Medicare and Medicaid Services have taken some steps to reduce the regulatory burden. In particular we applaud proposed rule changes to the HIPAA Privacy Rule, mentioned above, and to EMTALA rules.

I appreciate the opportunity to testify today and acknowledge where improvements have been suggested and highlight areas of continuing need for regulatory reform.

Thank you to you and your staff for your focused attention on these issues.