TO: Hillary Rodham Clinton
FROM: Jennifer Klein
DATE: 7/7/95
RE: Remarks for the Reinventing Health Care Regulation Event

If you have a chance to take a look, here is a draft of your remarks for Tuesday's regulatory review event. Your remarks lay out the problem and put the regulatory reform efforts in the larger context of the current debate about Medicare and Medicaid. Steve Gleason will talk about the impact of these changes (especially the elimination of the physician attestation form) on health care providers. (Apparently, the staff at Mercy Hospital actually cheered when they found out they will no longer have to fill out the form!) The Vice President will talk about how this fits in with his Reinventing Government Initiative.

I have included some fairly political comments on page 2. Melanne agreed with this approach, but I wanted to be sure you feel comfortable with it.

P.S. Thanks for meeting my parents! They (not surprisingly) thought you're wonderful.

FIRST LADY HILLARY RODHAM CLINTON
REINVENTING HEALTH CARE REGULATION EVENT
THE WHITE HOUSE
JULY 11, 1995

[Acknowledgments: Vice President Gore, Secretary Shalala (who could not be here today), HCFA Administrator Bruce Vladeck, Dr. Steve Gleason and the National Health Policy Council.]

Thank you all for joining us today. And thank you again for all of the work you did last year on health care reform and continue to do.

Last year, you taught all Americans that while we have the highest quality health care system in the world, that system is too complicated. And that while we boast some of the most talented and dedicated health professionals and advanced research institutions, those professionals and institutions are overburdened by paperwork, red tape and needless regulation.

As part of our reform efforts last year, we looked for ways to streamline regulations and simplify the health care system. At the same time, Vice President Gore's Reinventing Government Initiative began eliminating unnecessary regulatory burdens in all areas of government. Today's meeting represents the perfect marriage of those two efforts. One step in an ongoing effort to free doctors, hospitals and other health care providers to do what they were trained to do. One step to maintain and enhance quality in our health care system -- not by micromanaging but by measuring results.

Hospitals today hire four new administrators for every new doctor -- four to one -- simply to handle the avalanche of insurance forms and paperwork. Doctors' offices spend 80 hours a month on administration. That's time not spent with a child who needs a check-up; time not spent diagnosing a patient with bronchitis. I will never forget talking to a nurse last year who summed it up for me. She said she had gone into nursing to care for people. If she had wanted to be an accountant she would have studied accounting and worked for an accounting firm. Instead, after training to be a nurse, she spent nearly 50 percent of her time filling out forms.

Even worse, many of you have made, or watched the institutions where you work make, difficult choices to hire more bookkeepers and clerical people while laying off nurses and medical technicians. That is an unacceptable choice that no physician, hospital or nursing home should have to face.

We can make a significant start on simplifying the health care system by improving how the Federal health programs do business. In recent months the health care debate has centered

around the need to reform Medicare and Medicaid and to get spending under control. Everyone agrees that Medicare and Medicaid can be improved. And everyone agrees that Federal health spending is growing too fast. Over the next five years alone, almost 40 percent of the growth in Federal spending will come from the rise in Federal health care costs. They are growing faster than GDP. Faster than overall inflation. Faster than almost all other items of government spending.

But, as the President has been saying, there is a right way and a wrong to slow the growth in Medicare and Medicaid spending and to address the problems in these programs. The Republican proposal to take deep Medicare cuts to pay for tax breaks for the wealthiest Americans is the wrong way. Their Medicaid block grant proposal -- under which children and elderly and disabled Americans would lose coverage -- is the wrong way.

Instead, we need to remember that Medicare and Medicaid have lifted millions of Americans out of poverty and have helped millions more manage to pay for desperately needed health care services. The right way is to improve and strengthen these programs and make them more efficient. That's why the President proposed a budget that reaches balance in ten years but that has half of the Medicare and one-third of the Medicaid savings in the Republican plan. That's why the President's budget takes only the Part A cuts needed to strengthen the Medicare Trust Fund rather than playing on fears about the insolvency of the Fund to slash Medicare spending to pay for other priorities. And that's why the President's budget takes the first steps toward health care reform.

But even as this debate continues, there are changes that we can make in Federal health care programs right now. Changes that will improve these programs -- and improve your ability to work with these programs -- bit by bit, piece by piece. We can simplify the system and regulate the right way, without compromising quality.

In the past two and a half years we've made progress. [Insert examples.] The reforms that the Vice President will outline today are part of an ongoing process. I hope that we can build off of the work we've done so far and leave here with the promise and the challenge of continuing a working relationship that involves the White House, HHS in Washington, its regional offices, those of you working in communities across the country, and those of you who represent health care professionals nationwide. With your help, we can continue to identify unnecessary and burdensome regulations and work together to simplify and improve our health care system.

[Introduce Steve Gleason.]

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"I am determined to see reform of our regulatory system, so that it costs less, meddles less, and puts more responsibility in the hands of the people themselves."

President Bill Clinton -- February 21, 1995

"We can improve the relationship between regulators and the people they regulate to achieve our national goal of a robust economy that also protects public health and safety."

Vice President Al Gore -- February 21,1995

OVERVIEW

Introduction

The Clinton Administration has made reforming the Federal government's regulatory process a top priority. Consistent with this commitment, President Clinton and Vice President Gore asked Health and Human Services Secretary Donna Shalala to assist in meeting this priority by carefully examining the regulatory requirements of the Health Care Financing Administration (HCFA).

As part of the Vice President's reinventing government initiative, HCFA has reviewed its regulations to determine which requirements could be reduced or eliminated without compromising Medicare and Medicaid beneficiaries' access to quality health care. This report contains recommendations resulting from the review of HCFA's regulations.

Agency Overview

The Health Care Financing Administration (HCFA) has a major responsibility for health care financing and quality oversight of health care providers. HCFA operates the Medicare program, serving nearly 37 million beneficiaries, and in partnership with State governments, the Medicaid program, which serves another 36 million beneficiaries.

HCFA ensures that program beneficiaries are aware of the services for which they are eligible and that those services are accessible, meet acceptable standards of quality, and are delivered in an

- In March, 1994, HCFA published a regulation that replaced the requirement for physicians to provide hospitals annually with a signed acknowledgment concerning penalties for misrepresenting certain information with a one-time signing requirement at the time a physician is initially granted hospital admitting privileges. Almost 24,000 hours of physician time will be saved. One major medical association characterized this change as one that will alleviate the "hassle factor" for physicians and an important step toward restoring mutual trust between the Federal Government and the medical profession.

- HCFA is totally redesigning its system to pay claims for Medicare services. The development of the Medicare Transaction System (MTS) will increase control of program expenditures, and improve services to beneficiaries and providers. Final contracts for the analysis, design, development, testing, and implementation of the MTS were awarded January and March 1994.

  Presently providers must cope with 9 different claims processing systems operated by 72 insurance companies at 57 sites. This integrated, national system will replace the diverse existing systems and significantly simplify administrative operations for beneficiaries, providers, and the Medicare program.

- HCFA has re-invented the evaluation of Medicare contractors. The newly restructured Medicare contractor performance evaluation establishes Medicare beneficiaries and medical care providers as integral partners in the evaluation process. It allows for greater flexibility in evaluating Medicare contractor operations and performance. The new evaluation began October 1, 1994.

- The nursing home monitoring and enforcement rule, effective July 1, 1995, strikes the critical balance between strengthening quality standards in nursing homes to meet the health and quality of life needs of residents, and providing flexibility to apply remedies that fit specific problems at nursing facilities. Overall, the rule (1) links enforcement remedies to deficiencies; (2) motivates facilities to remain in compliance with Federal requirements that promote the quality of care and quality of life in nursing homes; (3) promotes survey and enforcement consistency; and, (4) avoids unnecessary burden on facilities through the use of an informal dispute resolution process.

  Draft language

  As has been the case throughout the development of this regulation, the Department of Health and Human Services will consult extensively with interested parties in the implementation of the enforcement regulation. An extensive monitoring system will provide data to evaluate the implementation process and the impact of the regulatory change. The structure of the enforcement process permits time to observe the regulations in action before major penalties are assessed. Adjustments to the process, policies, and procedures will be made if data indicates that they are needed.

- Obtaining Medicaid home and community-based services waivers was simplified in a rule published July 25, 1994. The final rule enables States to offer a wide variety of home and

efficient manner. HCFA also ensures that health care providers of services meet approved standards, and that program funds are used efficiently.

Regulatory Reform Principles

Regulatory reform can only be accomplished by keeping in touch with the needs of customers. For HCFA, this means knowing what beneficiaries want and need and knowing how we can work with our partners to fulfill and even exceed the expectations of our customers, our beneficiaries.

To help with the regulatory review process, HCFA relied on three basic principles that help define the Agency's new and improved customer service mission.

- Communicate not dictate -- The number one tenet of this principle is to communicate -- through listening and consulting, thereby increasing our understanding of what our customers need, what they like and dislike about our programs, and how we can serve them better overall. This principle says that HCFA will consult with our partners and beneficiaries about how our programs and policies should improve, instead of dictating such changes to them as has been done too often in the past. When changes are a result of legislative initiatives, HCFA will consult with partners and stakeholders on the full range of implementation issues that need to be addressed.

- Educate rather than inundate -- Top rate customer service also means making sure that customers understand our programs and policies. Providing reams and reams of information is not enough -- and probably not effective. The "new" HCFA is committed to educating instead of inundating. This principle ensures that HCFA will educate our customers by developing effective educational techniques and disseminating information about how our programs operate rather than inundating them with information that is difficult to understand and doesn't speak to their needs.

- Innovate more than regulate -- HCFA's new and improved mission of customer service is driven by innovation more than regulation. This means that HCFA will rely upon innovation in program operations and administration more than regulation to foster improved customer service capabilities. For example, by streamlining Medicare claims processing and information exchange, the Medicare Transaction System will make electronic interaction with Medicare easier for providers and beneficiaries and will enable Medicare contractors to devote more time to customer service activities.

Accomplishments

During the Clinton Administration, HCFA's regulatory improvements include:

community-based services as cost-effective alternatives to more expensive institutional care. Without this regulatory movement, joint State and Federal efforts to expand opportunities to provide cost-effective alternatives to institutional care would have been frustrated. The regulatory provisions were worked out in collaboration with the States (through the National Governor's Association).

Regulatory Reform Initiatives

The following proposals are the major HCFA initiatives that have evolved from our commitment to the regulatory reform process. In some cases, recommendations reflect actions based on collaborative efforts, including public consultation with industry groups, beneficiary organizations, and State associations and agencies. All of these projects were designed to cut unnecessary red tape and burdensome regulations. Most importantly, they demonstrate HCFA's customer-focus and responsiveness to the changing needs of all its customers and partners.

*1. **Physician Attestation:*** Eliminate the physician form required to certify the accuracy of all diagnosis and procedures before submission for payment by Medicare.

*2. **Clinical Laboratory Improvement Amendments:*** Reduce burden and improve the CLIA system by rewarding good performance by laboratories, creating incentives for manufacturers to develop more reliable testing equipment, allowing private organizations that meet certain standards to accredit laboratories, and using proficiency testing as an outcome measure to monitor laboratory performance.

*3. **Outcome Performance Measures:*** Change current regulations that focus solely on requirements for measuring processes, rather than outcomes of care. Changes involve:

- Home Health Agency Conditions of Participation
- Medicare Hospital Conditions of Participation
- ESRD Facility Conditions of Coverage
- Rules for ESRD Facilities - A Pilot for Good Performers
- Elimination of Personnel Requirements for Excellent ESRD Facilities

*4. **The HCFA-1500 Form:*** Mandate participating Federal Employee Health Benefit Plan carriers use the HCFA-1500 form for physicians' and other practitioners' claims. The HCFA-1500 is used by physicians and others to submit claims for reimbursement of health care services under Medicare.

*5. **Annual Preadmission Screening and Annual Resident Review:*** Eliminate the requirement that mentally ill and mentally retarded nursing home residents are assessed annually. The preadmission screening for these residents is retained.

6. ***Nurse Aide Training and Competency Evaluations:*** Permit States to approve nurse aide training and competency evaluation programs offered in nursing homes.

HCFA INITIATIVES

1. Physician Attestation

Background: Since the Medicare hospital inpatient prospective payment system (PPS) was implemented by HCFA in 1984, HCFA regulations have required physicians to sign an "attestation form" for each Medicare patient discharged from a hospital. The form certifies the accuracy of the diagnoses and procedures for each patient. This information is used to ensure that the correct coding is on the claim, the correct diagnosis-related group (DRG) can be assigned, and the proper Medicare payment can be made.

Feedback from physicians, hospitals, and intermediaries have told us that obtaining the physician's signature is burdensome and results in billing delays that hurt hospital cash flow and hinders service to the beneficiary. Peer Review Organization (PRO) review of attestations has resulted in fewer that a 0.01% denial rate of sampled claims. In addition, the improvement in hospital record keeping and coding sophistication make the hospitals the appropriate focus for combating fraud and abuse.

Proposed Solution: Eliminate the form requirement and instead hold hospitals responsible for the accuracy of their diagnoses and procedures. With improved technology and software coding capabilities, hospitals are more equipped than ever to combat billing fraud and abuse, the form's original purpose. This change, which can be implemented by regulation, will have the following benefits:

Impact:

- Reduces paperwork burden and "hassle" on physicians and hospitals.
- Decreases administrative costs for hospitals.
- 11 million forms will be eliminated.
- Almost 200,000 hours of physician time will be saved.
- Hospitals will have improved cash flow and reduced labor costs by approximately $22,500 per hospital per year.

Implementation and Timeline: HCFA will publish this final regulation September 1, 1995.

2. Clinical Laboratory Improvement Amendments

Background: The Clinical Laboratories Improvement Amendments (CLIA) of 1988 established baseline quality standards that ensure the accuracy, reliability, and timeliness of laboratory testing. These requirements are based on the complexity of the test performed, rather than where the test is performed. Compliance with the standards is determined through on-site inspection.

HCFA and the Centers for Disease Control and Prevention, which share responsibility for the CLIA program, continually review ways to reduce the burden and improve the entire CLIA system. A flexible survey system that employs data analysis to target good performers and allow for self-attestation and off-site review has already been initiated for certain laboratories. HCFA has reduced information requirements and eliminated unnecessary paperwork and has taken steps to reduce personnel requirements. HCFA also revised and streamlined the inspection process. Additional burden reductions are being undertaken that will virtually eliminate oversight for certain laboratories, establish performance standards in place of process requirements, and use information and education as a substitute for sanctions.

Proposed Solutions:

1. Waive the routine 2-year survey of users of "black box" technology, conducting surveys only if there are indications of problems or complaints. ("Black box" technology refers to simple and easy to use test systems that have demonstrated accuracy and precision through scientific studies.) We will develop and implement criteria for accurate and precise "black box" technology that will be followed to determine if the technology qualifies for waiver of the routine 2-year survey. A small number of surveys will be conducted to validate the criteria for determining "black box" technology and assure quality.

   Impact:

   - Creates incentives for manufacturers to develop more reliable testing equipment by stimulating demand for accurate and precise technological testing systems.

   - Reduces paperwork and costs for providers, especially for physician office laboratories, as well as costs of program management.

   Implementation and Timeline: Proposed rules will be published September 1995.

2. Clarify and expand the waiver criteria and streamline the waiver process so that CLIA regulations can be waived for more tests. CLIA requirements will be waived for tests approved for home by the FDA -- that is, tests that do not require trained personnel.

Impact:

- Decreases burden, especially for physician office laboratories because of less regulatory oversight.

- Increases access to greater variety of tests. Physician office laboratories may expand the range of tests they perform without an increase in costs/burden.

- Creates incentives for manufacturers to develop more test systems that meet the clarified waiver criteria and criteria for approval for home use.

- Eliminates inspection fees for many of the 60,000 physician office and other small laboratories not now waived who decide to perform only tests from the expanded waiver category.

- Many additional laboratories will face lower inspection fees because, while they will continue to perform non-waived tests, many more tests will fall into the expanded waiver category.

Implementation and Timeline: Proposed regulations will be published in September 1995.

3. Use performance standards and require less frequent on-site inspections (surveys) of excellent performers. Approve private accrediting organizations for deemed status when their accreditation standards are as stringent as CLIA. Exempt laboratories from CLIA requirements when the State where they are located has requirements equal to or more stringent than CLIA's.

Impact:

- Reduces inspection burdens.

- Rewards good performers with fewer inspections. This is a positive incentive to improve performance.

- Approving organizations for deemed status offers laboratories oversight by peers.

- Approving States for CLIA exemption allows expanded role for States with strong licensure programs.

Implementation and Timeline: To date, notices to approve four accrediting organizations (College of American Pathologists, Joint Commission on Accreditation of Healthcare Organizations, Commission on Office Laboratory Accreditation, and the American Society of

Histocompatibility and Immunogenetics) and the State of Washington have been published. Notices for two additional accrediting organizations and one additional State are pending. Final rules to eliminate redundancies or unnecessary requirements for federal review and approval will be published in March 1996.

4. Use proficiency testing (PT) "failures" for education and as an outcome indicator in laboratory quality. (PT is testing samples of known values to assess the accuracy of a laboratory's results.) Sanctions (for example, loss of Medicare payment or loss of approval to do testing) are imposed only in cases of immediate jeopardy or when the laboratory has refused to correct the problem or has had repeated failures on proficiency testing.

   Impact:

   - Less intrusive than traditional regulation and oversight.

   - Allows use of proficiency testing as an outcome measure to monitor laboratory performance, and provide laboratories with feedback on test quality and an incentive to improve performance.

   - Minimizes the fear of sanctions in 60,000 non-waived laboratories.

   Implementation and Timeline: A proposed rule will be published in March 1996.

3. Outcome Performance Measures

Background: Medicare, as a purchaser of health care, requires hospitals, home health agencies (HHAs), and End-Stage Renal Disease (ESRD) facilities to meet health and safety requirements to participate in the Medicare program. Historically, these requirements measure "process" (procedural and administrative systems as proxies for quality health care) rather than "outcomes" (evaluations of actual patient care) and the adequacy of quality management programs.

HCFA is committed to changing current regulations that focus solely on requirements for measuring processes. The Agency realizes that not focusing on outcome measures results in several inherent problems. First, regulatory requirements vary by type of facility and provider even when the services provided in each facility are the same, creating inequities and inappropriate incentives. Second, without outcome measures, there is very little information available for consumers on the quality of care at a given facility. Third, by law, HHAs must be surveyed yearly--even though historical data show that this frequency is excessive for many HHAs and does not improve care.

HCFA is revising regulations for hospitals, home health agencies, and End-Stage Renal Disease facilities, that would address these issues and eliminate unnecessary process requirements and focus on the outcomes of care.

Proposed Solution: Eliminate unnecessary process requirements and instead develop outcome-based performance standards; collect and analyze patient care data needed for continuous quality improvement and performance evaluation; increase consistency of requirements across providers; and ask the customer to provide input on what the outcome measures should be, and to evaluate the services they received. We are seeking legislation to give us flexible survey cycles.

Impact:

- Eliminating unnecessary process requirements for compliance will reduce compliance and survey burdens and make it possible to focus on actual patient care.
- Educating the consumer will produce a strong, non-regulatory force to improve quality of care.
- Powerful data will be available to regulators and providers.
- Produces savings because providers are free to achieve high quality outcomes in the most cost-effective manner.

Outcome Performance Measures Initiatives

HCFA is currently involved in the following new initiatives that focus on the concept of

"Outcomes Performance Measures" and the consensual approach to developing regulations.

Home Health Agency Conditions of Participation:

HCFA is developing revisions to the Medicare Home Health Agency (HHA) conditions of participation. The purpose of the revision is to place greater emphasis on patient outcomes while reducing the current emphasis on process requirements (e.g., elaborate professional qualifications and other "paperwork" requirements) and enhancing an HHA's flexibility in meeting patient needs. The Agency has actively involved home health beneficiaries, providers, physicians, professional organizations (American Association of Retired Persons, National Association for Home Care, American Federation of Home Health Agencies, American Medical Association, Visiting Nurses Association of America, American Academy of Home Care Physicians), States (State Survey and Medicaid Agencies), and intermediaries in order to receive input on developing revisions to the conditions of participation. A work group of HCFA staff and representatives of Medicare beneficiaries, home health providers, physicians, and State Survey Agencies will develop a Standard Core Assessment Instrument for use in home health care. The use of this tool is central to HCFA's efforts to place the emphasis of survey and enforcement on patient outcomes.

Implementation and Timeline: HCFA will publish a proposed rule in September 1996.

Hospital Conditions of Participation:

HCFA is revising the current hospital conditions of participation to center on the patient, support a cross-functional approach to patient care, and focus on quality. In developing these revisions, HCFA has worked closely with organizations representing hospitals, practitioners, patients, and States and has already distributed informal pre-regulatory drafts to approximately 70 outside groups for comment.

Implementation and Timeline: HCFA will publish a proposed rule in January 1996.

End Stage Renal Disease (ESRD) Conditions of Coverage:

HCFA's ESRD Conditions of Coverage (COC) have not been comprehensively revised since their original implementation in the late 1970's. The current COC are primarily focused on process-oriented requirements, and do not provide adequate support for a modern survey system based on an outcome-oriented approach. Under the current regulation, facilities have a substantial paperwork burden. As a result, revised regulations must be issued to increase facility flexibility and to bring the ESRD COC up to current standards of practice in the ESRD community. The revised COC will address the outcome-oriented, patient-centered standards process where

appropriate, reflect innovations in the dialysis and transplant community, and address new issues such as adequacy of dialysis to ensure that the Medicare beneficiary is receiving the most progressive quality of care possible. Thus, HCFA's emphasis will be on the total patient experience with dialysis, including patient functional well-being and continuous quality improvement (CQI). The revised regulations will include development of performance expectations for the facility that result in quality, comprehensive care for the dialysis patient.

Implementation and Timeline: HCFA will publish a proposed rule in March 1996.

Rules for ESRD Facilities - A Pilot for Good Performers:

HCFA is conducting a pilot project to apply a different, less prescriptive set of rules to excellent ESRD facilities. Under the pilot project, an ESRD facility's performance will be measured using only three key patient care outcome indicators. First, these indicators will be used in place of the current certification standards, which are largely structure and process requirements. Second, the pilot project will focus on helping facility staff's use outcome measures in an ongoing way to improve the care provided to dialysis patients. Third, facilities that document sustained achievement in the outcome indicators over six consecutive months will be awarded a HCFA certificate of excellence.

The indicators measure the quality of hemodialysis in three areas critical to the health of the patient: adequate dialysis, control of anemia, and adequate water supply. They will be used by the facilities to monitor the condition of each dialysis patient and to achieve improvement in the patient's health status. For the pilot project, excellence will be identified through a process focused on the quality indicators. The process will look at whether facilities have an internal quality monitoring and monitoring system, whether the results of such monitoring are documented, and whether results are sustained. The facilities that qualify in this pilot will have established certain internal quality control mechanisms in order to participate. Routine surveys of these facilities will be waived. Surveys will be conducted in response to complaints about the quality of care or if the data indicate a potential serious problem.

Information about project results will be packaged in brochures and newsletters so that ESRD patients and non-participating ESRD facilities will be aware of the results. In this competitive industry, a successful project will stimulate many other providers to seek recognition as "EXCELLENT" facilities.

ESRD facilities will be notified of their eligibility to participate and participation will be voluntary. The pilot will be limited to facilities in the States of Colorado, Idaho, Montana, and Washington.

Implementation and Timeline: Planning for this pilot is underway. Regulations to permit this

pilot will be published in November 1995.

Elimination of Personnel Requirements:

HCFA is conducting a pilot project that will evaluate the impact of the elimination of Medicare personnel requirements for ESRD facilities. Currently, the Medicare conditions for coverage for ESRD facilities include fairly detailed specifications for several types of personnel employed in furnishing ESRD services to Medicare beneficiaries. For example, the medical director of the facility must be a physician, board eligible in internal medicine; the nurse in charge must have 12 months of clinical experience, with 6 months experience with ESRD patients; the social worker must be master level educated, etc. Over the years, HCFA has received comments from the industry both in favor of elimination of the personnel requirements and in favor of strengthening them. Those in favor of relaxing the requirements commonly cite the difficulty rural facilities can face in recruitment of personnel with the requisite experience. They believe that the job does not require the level of experience and education prescribed in order to perform adequately. Those in favor of maintaining personnel requirements cite the medical condition of ESRD patients as justification for the skills level requirements. They express concern that if the personnel requirements are weakened or eliminated that ESRD facilities, most of which are proprietary entities, would hire less experienced and more inexpensive personnel to provide care that is of inferior quality.

The pilot project would be conducted in concert with another proposed project establishing new rules for historically good ESRD performers (see above) being conducted by HCFA's Seattle Regional Office. HCFA will collect information regarding the skills level of all personnel employed by those facilities participating in the project. Facilities would be informed that as part of the project, Medicare would not apply any of the personnel requirements contained in the conditions for coverage. At the end of the two-year project period, HCFA will recollect information regarding the education and experience level of all the facility's staff and evaluate the impact of the changes on predetermined measures of quality of care.

Implementation and Time line: Planning for this pilot is underway. Regulations to permit this pilot will be published in November 1995.

4. The HCFA-1500 Form

Background: The HCFA-1500 form is currently used by physicians, other practitioners, and DME suppliers to submit claims for Medicare reimbursement of health care services. HCFA-1500 is also used by many other insurers for claims submission. Although many Federal programs require the use of the HCFA-1500, use of the form is not required by the Federal Health Benefit plan (FEHBP). In addition, instructions for the form vary across programs.

Proposed Solution: The Office of Personnel Management (OPM) will require participating FEHBP carriers to use the HCFA-1500 form for physicians' and other practitioners' claims.

Impact: Physicians will be able to use one form to submit claims for services provided to many patients.

Implementation and Time frame: OPM will phase in the use of the HCFA-1500 over four years, beginning January 1996.

5. Preadmission Screening and Annual Resident Review (PASARR) of Mentally Ill and Mentally Retarded Residents

Background: Nursing homes under Medicare and Medicaid are currently required by law to conduct an initial assessment of each resident within 14 days of admission, with a reassessment whenever a significant change in condition occurs but in any event at least once a year. In addition, there is a statutory requirement that for persons with serious mental illness or mental retardation entering a nursing home the State is required to conduct: (1) a preadmission screening to assure that the individual is being appropriately placed in a nursing home, and (2) an annual reassessment to assure that the patient continues to be appropriately diagnosed and treated.

Proposed Solution: Legislation would be proposed to eliminate the duplicate annual assessment. Resident assessments and reassessments required under the general nursing home requirements are entirely adequate to assure that residents continuing needs are properly assessed and met. Preadmission screening, which appropriately deters inappropriate admissions, would continue.

Impact: By eliminating the redundant annual PASARR reassessment, costly duplication of effort by States would be reduced and nursing facilities would be relieved intrusive annual inspections.

Implementation and Timeline: Legislation will be proposed.

6 7. Nurse Aide Training and Competency Evaluations

Background: To assure quality of care in nursing homes, current law prohibits nursing homes from using nurse aides that have not successfully completed a training or competency evaluation program. The statute requires the Secretary to establish requirements for the approval of nurse aide training and competency programs. The law further forces States to prohibit, for a period of two years, nurse aide training and competency evaluation programs operated by or in nursing homes that were subject to an extended survey or partial extended survey or certain other sanctions. (Extended or partial extended surveys are conducted as more intensive follow-up investigations after a routine survey has demonstrated that a facility is furnishing substandard care.)

When a facility's program has been disapproved, the facility may not even be the site of an aide program conducted by others during the time that the two-year penalty is imposed. The prohibition on approval of nurse aide training and competency evaluation programs causes a special problem for rural nursing homes where a community college or other training facility may be inaccessible to nurse aides. Rural facilities can face a serious shortage of trained and competent staff due to the expense and inconvenience of sending prospective aides to remote locations. Alternative training programs may not be available.

Proposed Solution: Specify that a State could choose to approve a nurse aide training and competency evaluation program offered in (but not by) a nursing home subject to an extended or partial extended survey or certain other sanctions if the State determines that there is no other nurse aide training and competency evaluation program offered within a viable distance. States would be required to provide ongoing oversight of these programs in the interest of patient health and safety.

Impact: This proposal would safeguard the availability of nursing homes which might otherwise stop participation in the Medicare and Medicaid programs as a result of losing a training programs' approval. It would also make it easier for nurse aides to obtain the training they need to provide quality services to our beneficiaries.

Implementation and Timeline: Legislation will be proposed.

Conclusion

Under President Clinton's leadership, HCFA has made communication, cooperation, and partnership the guiding principles of the regulatory process, replacing the adversarial environment that often existed in the past. At a time when the American health care system is undergoing dramatic changes, HCFA is committed to "putting the federal government's customers -- the American people -- first". We are pleased to report that the initiatives described in this report represent just the beginning phases of HCFA's ongoing support of the National Performance Review efforts.

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First Lady's Remarks
ReGo 2 — HCFA Reform
July 11, 1995
(draft as of 07/03/95 9:39 AM— 750 words)

Thank you ladies and gentlemen. Thank you for joining Vice President Gore and me to unveil the reinvention of the Health Care Financing Administration.

(Acknowledgments from advance.)

While health care has a special place in my heart, when it come to reinventing government, there is nothing unique about health care. The same principles apply:

- We have to take a lesson from America's best run companies and ***put the customers first.*** We need to focus on the results that the American People want, and forget about following the rules just for the sake of following the rules.

- We have to ***cut out the red tape*** and the paper work that costs an enormous amount of time and money — red tape that sends a constant message to federal workers and to Americans everywhere that ***Washington knows best***, and that ***Washington doesn't trust you***. We have to stop treating full-grown Americans like children.

- We have to ***trust the people who are working on the front lines*** of American health care. As a general rule, they have more than enough common sense, they are creative and innovative, and they want to take care of their patients — otherwise they wouldn't have suffered through years and years of medical training.

- And when it comes to regulation, we have to change to a system that is based on ***partnership,*** rather than adversarial enforcement and punishment. In other words, the we ought to base our systems on the assumption that most doctors and hospitals want to help you — they want to make you well again — and only a very, very few are out to

use these-- what we learned in health care reform

Here's what's wrong w/ the health care system

flimflam you or to bilk the government. We can certainly design our systems to catch the few flimflam artists without punishing the vast majority of honest Americans.

Vice President Al Gore and his team — a group of dedicated federal workers who call themselves the National Performance Review — have been putting these principles to work for nearly two years.

- They are changing the way that the government buys things — no more $600 hammers — no more government specifications for ashtrays or chocolate chip cookies. Tomorrow's government uses common sense and commercial items.

- They're changing the way that the government is managed — no more industrial-age hierarchy with huge corporate headquarters and layer upon layer of wasteful micro-management. Tomorrow's government uses common sense and information-age teamwork.

- They are changing the way government regulates — whether it's to clean up the environment, or to keep workers safe and healthy, or any of the dozens of other high goals that Americans have chosen to pursue through government. No more mile-high stacks of incomprehensible rules — no more bureaucracy and red tape — no more nasty attitude of Washington-versus-America. Tomorrow's government uses common sense and partnership to achieve its regulatory goals.

The Clinton-Gore administration is creating tomorrow's government the right way. We're making it work better and cost less.

But, there is a wrong way to do it, too. The wrong way is to forget all about making it work better, and just hack away at the cost. People who don't seem to care whether government starts working better are missing a basic point about America.

In America, the government is not some force at work ***against*** the people. The government is ***for*** the people — and ***by*** the people. Government ***is the people*** of America working together to solve some of their biggest national problems.

But if government does not work well — if it does not solve the problems it sets out to solve — problems like crime or poverty, disease or ignorance, threats to our security or to our economy — then Americans loose faith in government. And when we do that we are loosing confidence in our own ability to take effective action together.

That is a crisis of confidence we face today. Thirty years ago, when asked if government could be trusted to do the right thing, 75% of Americans said yes. Today, it's less than 20%.

We have to restore our faith in government. We have to restore our faith in ourselves. That's why we have to make government work better — not just cost less.

And now, to tell you how one more part of government — the Health Care Financing Administration — is going to be working better and costing less, here is the man who has been down in the trenches fixing it, Vice President Al Gore.

MERCY HOSPITAL MEDICAL CENTER
Sixth & University · Des Moines, Iowa 50314

FAX TRANSMITTAL

DATE: 7/7

TO: ~~Patrick MARRIS (202) 632-0390~~
~~VP Office~~

TO: Jennifer Kline -456-2878

FROM: Liz Shannahan
Dr. Gleason
MEDICAL RECORD SERVICES

(515) _____ (Telephone Number)
(515) 248-8813 (Fax Number)

NUMBER OF PAGES (including transmittal sheet): _____

COMMENTS: This is the Form: Mercy had 11,127 Medicare discharges CY 1994. 555 Bed Hosp.

I'll call you soon.

MERCY HOSPITAL MEDICAL CENTER
400 University Ave. • Des Moines, Iowa 50314

MERCY HOSP. MED. CENTER
PHYSICIAN ATTESTATION STATEMENT
DATE 06/15/95

NAME [redacted] ACCT 000581S035150 MED REC NO 005049085
ADM/VST DATE 05/30/95 DIS/DEPART DATE ROOM/BED
DATE OF BIRTH 10/22/04 AGE 90 SEX F LOS 017 DSCH DISP
ATTENDING PHYSICIAN [redacted]

MDC 007 DISEASES AND DISORDERS OF THE HEPATOBILIARY SSTEM AND PANCREAS
DRG 193 BIL PROC W CC, EX ONLY CHOLCYST W/WO CDE
OUTLIER STATUS CHARGES 20823.64 REIMB 11750.37

ADMITTING DIAGNOSIS
574.51 CHOLEDOCHLITH NOS W OBST

PRINCIPAL DIAGNOSIS
1. 574.51 CHOLEDOCHLITH NOS W OBST

SECONDARY DIAGNOSES
2. 285.1 POST OP ANEMIA
3. 997.4 POST OP ILEUS
4. 576.1 CHOLANGITIS
5. 714.0 RHEUMATOID ARTHRITIS
6. 401.9 HYPERTENSION NOS

PROCEDURES			DATE
1.	51.41	CDE FOR CALCULUS REMOV	06/02/95
2.	51.10	ERCP	05/31/95
3.	38.93	VENOUS CATHETER NEC	05/30/95
4.	87.53	INTRAOPER CHOLANGIOGRAM	06/02/95

I CERTIFY THAT THE NARRATIVE DESCRIPTIONS OF THE PRINCIPAL AND SECONDARY DIAGNOSES AND THE MAJOR PROCEDURES PERFORMED ARE ACCURATE AND COMPLETE TO THE BEST OF MY KNOWLEDGE.

_____ _____
ATTENDING PHYSICIAN DATE

Here is draft release for Tuesday HCFA event.

As this has to be cleared by several offices--White House Press, Vice President, First Lady, HHS, HCFA and OIRA--I would appreciate your short edits by Noon, Monday, July 10 so I can get to work on the final product.

This release and the HCFA booklet will be handed out to the press at the event and be available for the later briefings.

Thanks for your help.

Mike Russell

Mike Russell, NPR Press
202-632-0150, ext. 153
632-0390 fax

DRAFT

THE WHITE HOUSE
OFFICE OF THE PRESS SECRETARY

FOR IMMEDIATE RELEASE
Tuesday, July 11, 1995

Contact: 202-632-0150

VICE PRESIDENT, FIRST LADY ANNOUNCE REFORM OF HEALTH CARE RULES
Less Paperwork, More Time For Patient Care Will Result From Reinvented Regulations

Vice President Al Gore and First Lady Hillary Rodham Clinton today unveiled a series of health care regulatory reforms within the Health Care Financing Administration (HCFA), an agency of the U.S. Department of Health and Human Services. The changes include cutting burdensome paperwork requirements--giving health care providers more precious time for patients--and the removal of roadblocks to innovation and cost-cutting.

Highlights of the HCFA reforms include:

- Nursing home regulation to focus on quality of care rather than enforcement of process standards. Will allow flexibility to apply remedies that fit specific problems at nursing facilities.
- Physicians Medicare "attestation" form to be eliminated. Result is elimination of 11 million forms and savings of 200,000 hours of physician time. Will cut labor costs $22, 500 per hospital per year.
- Streamlining of lengthy laboratory equipment certification and inspection process while maintaining accuracy and reliability standards. Creation of incentives for manufacturers to develop more reliable equipment.
- Refocus Medicare providers toward actual patient care by changing unnecessary process requirements to outcome-based performance standards. Produces savings as providers are free to achieve high quality outcomes in most cost-effective manner.
- Removal of barriers to HMOs in rural areas. Will improve access to care for Medicare beneficiaries.

Vice President Gore said: "When it comes to reinventing government, health care--although a more personal issue--isn't that different from other national problems. We need to focus on first class care rather than forcing our doctors and caregivers to worry more about staying within the lines of regulation. They shouldn't be forced to look over their shoulders but instead be allowed to use the best of innovation and inspiration to provide quality health care."

"We have to change to a system that is based on partnership, rather than enforcement and punishment," said Mrs. Clinton. "We ought to base our system on the assumption that most doctors and hospitals want to help--they want to make you well again--and only a very, very few are out to bilk the government. This reinvention of regulations is a major step in our goal of giving Americans the very best health care system."

Donna E. Shalala, Secretary of the Department of Health and Human Services, said: "I'm expecting Melissa to come up with a quote here that will get me in all the top papers across the country."

(insert short quote)

"This is where my quote should go," said Bruce C. Vladeck, Jr., HCFA Administrator.

(insert short quote)

The Health Care Financing Administration operates the Medicare program, oversees state-federal Medicaid plans, and is responsible for the quality of health care provided by 60, 000 hospitals, nursing homes, home health agencies and other facilities. HCFA also oversees the quality of 152,000 testing laboratories in the U.S. and the federal licensing of health maintenance organizations (HMOs).

TENTATIVE SCHEDULE FOR PHYSICIANS (Gleason folks)

Tuesday, July 11

NOTE: You should come to the Pennsylvania Avenue entrance to the Old Executive Office Building at the corner of Pennsylvania and 17th Street (this building is right next to the White House). Please try to arrive by 9:00 am to allow for your security clearance.

9:30am - 10:45am	Budget/Issues Briefing Room 450, Old Executive Office Building (This will include a substantive briefing on Medicare and Medicaid)
11:00am - 11:45am	Special Event — Political mtg with 1st Lady The White House
11:45am - 12:30pm	Lunch (on your own)(many local sandwich shops near the Old Executive Office Building)
12:45pm - 2:00pm	Healthcare Regulatory Reform Event with the Vice President and First Lady Room 450, Old Executive Office Building
2:00pm - 3:30 pm	Potential press interviews for individual physicians (for those who are able to stay during this time period, we will try to arrange press interviews with your home state press).

ADDITIONAL NOTE: We apologize for changes in the schedule which have moved the length of the meetings into the afternoon. We hope this will not inconvenience anyone's scheduled travel plans.

HEALTH CARE FINANCING ADMINISTRATION

7203

John Morales
John Morrell
6

Claudia Cooley
3/11/44

Call Brad Yarwood

5-7316

350

ADDRESSEE: Bob Knisely 366-9777 Jennifer Klein 456-2599 Nancy Ann Min Molly Poag Allison Eydt 395-9128 **PHONE:** Doug Farbrother	**FROM:** Jennifer Boulanger OFFICE OF THE ADMINISTRATOR 200 INDEPENDENCE AVE., S.W. ROOM 314G WASHINGTON, DC 20201 PHONE: 202-690-6726 FAX : 202-690-6262

TOTAL PAGES:	ADDRESSEE'S FAX MACHINE NUMBER:	DATE:

REMARKS:

July 6, 1995

MEMORANDUM TO PHYSICIAN ORGANIZATIONS

FROM: MARILYN YAGER, SPECIAL ASSISTANT TO THE PRESIDENT
OFFICE OF PUBLIC LIAISON
202/456-6683

RE: INVITATION TO JOIN THE VICE PRESIDENT AND FIRST LADY FOR A HEALTH CARE REGULATORY REFORM EVENT.

We wish to invite your organization to join Vice President Al Gore and First Lady Hillary Clinton for the official release of our Health Care Regulatory Reform recommendations on Tuesday, July 11.

As part of the discussions the First Lady had with many of your organizations during the health care reform deliberations, and more recently as part of the Vice President's reinventing government initiative, HCFA has reviewed its regulations to determine which requirements could be reduced or eliminated. Although we view this process as an ongoing effort, the report to be released on July 11 will contain recommendations resulting from the initial phase of the regulatory reform review.

Please join us for this event on **Tuesday, July 11, at 12:45 pm in Room 450** of the Old Executive Office Building. Due to space limitations each organization will be **limited to five** seats. Attendees should arrive by 12:30 pm using the Pennsylvania Avenue entrance to the Old Executive Office Building at the corner of Pennsylvania and 17th Street.

Please fax (202/456-6218 or 202/456-6682) the full legal names of the individuals representing your organization, their social security numbers, and birth dates by Monday morning at 12:00 noon. Should you have any questions please contact me or my assistant Dani Rose.

In addition, there will be a <u>private meeting</u> with the First Lady and the most senior representative from each physician organization (preferably the President or Executive Director) at 12:00 noon in Room 472, prior to the event on July 11. Please let me know who is the <u>one person</u> representing your organizations at this meeting.

"I am determined to see reform of our regulatory system, so that it costs less, meddles less, and puts more responsibility in the hands of the people themselves."

President Bill Clinton -- February 21, 1995

"We can improve the relationship between regulators and the people they regulate to achieve our national goal of a robust economy that also protects public health and safety."

Vice President Al Gore -- February 21,1995

OVERVIEW

Introduction

The Clinton Administration has made reforming the Federal government's regulatory process, while maintaining Medicare and Medicaid beneficiaries' access to quality care, a top priority. Consistent with this commitment, President Clinton and Vice President Gore asked Health and Human Services Secretary Donna Shalala to assist in meeting this priority by carefully examining the regulatory requirements of the Health Care Financing Administration (HCFA).

As part of the Vice President's reinventing government initiative, HCFA has reviewed its regulations to determine which requirements could be reduced or eliminated without compromising Medicare and Medicaid beneficiaries' access to quality health care. This report contains recommendations resulting from the review of HCFA's regulations.

Agency Overview

The Health Care Financing Administration (HCFA) has major responsibility for health care financing and quality oversight of health care providers. In particular:

- HCFA operates the Medicare program, serving nearly 37 million beneficiaries.

- HCFA and State governments in partnership operate the Medicaid program, which serves another 36 million beneficiaries.

- HCFA oversees the quality of care provided to Medicare and Medicaid patients in hospitals, nursing homes, home health agencies, hospices and other facilities. Some 60,000 providers are surveyed each year under HCFA auspices.

- HCFA also administers the Clinical Laboratories Improvement Act (CLIA) and, together with the Centers for Disease Control, oversees the quality of laboratory testing for the entire Nation. Approximately 152,000 laboratories, which perform billions of tests each year, are subject to this Act.

- Under Title XIII of the Public Health Service Act, HCFA provides Federal qualification of health maintenance organizations (HMOs). At present, 52 to 54 percent of the HMOs in the country have Federal qualifications.

- HCFA provides Federal oversight of State regulation of Medigap insurance, the insurance that supplements Medicare benefits.

HCFA works with a number of partners in administering its programs:

- HCFA contracts with 73 fiscal intermediaries and carriers to assist in operating the Medicare program by providing claims payment, medical review, and provider and beneficiary services. Fifty-three Peer Review Organizations engage in quality improvement for Medicare professional services.

- HCFA works with the governments of all of the States, the District of Columbia, and territories in running the Medicaid program.

- State survey agencies, under contract to HCFA, inspect CLIA laboratories and providers participating in Medicare and Medicaid.

- HCFA contracts with 18 End-Stage Renal Disease Networks which oversee the quality of, and access to, dialysis services provided to beneficiaries qualified for Medicare because of their End-Stage Renal Disease (kidney failure).

- HCFA contracts directly with 195 managed care organizations providing Medicare Part A and B services directly to 2.8 million beneficiaries.

HCFA, with its 10 regional offices, ensures that program beneficiaries are aware of the services for which they are eligible and that those services are accessible, meet acceptable standards of quality, and are delivered in an efficient manner. HCFA also ensures that health care providers of services meet approved standards, and that program funds are used efficiently, without fraud or abuse.

HCFA Mission and Goals

In February 1994, HCFA prepared a detailed Strategic Plan, which it is now implementing, that sets forth our mission statement, vision statement, goals and objectives, and the specific strategies we will pursue to reach them. HCFA's Strategic Plan, with its customer service focus, has become the Agency's blueprint for the future.

HCFA's mission statement, which clearly expresses the Agency's conviction that HCFA exists to serve its beneficiaries, is:

"We Assure Health Care Security for Beneficiaries"

To HCFA health care security means access to affordable and quality health care services; protection of the rights and dignity of beneficiaries; and, provision of clear and useful information to beneficiaries and providers to assist them in making health care decisions.

Building on the mission, HCFA defined its vision of HCFA's future role as:

We Guarantee Equal Access to the Best Health Care"

The vision reflects our commitment that all individuals will be given an unconditional assurance of having the same opportunity to have their health care needs met, regardless of location, income, or other circumstances; and, the quality of health care they receive is the best that can be provided.

Regulatory Reform Principles

Regulatory reform can only be accomplished by keeping in touch with the needs of customers. For HCFA, this means knowing what beneficiaries want and need and knowing how we can work with our partners to fulfill and even exceed the expectations of our customers, our beneficiaries.

To help with the regulatory review process, HCFA relied on three basic principles which help define the Agency's new and improved customer service mission.

- Communicate not dictate -- The number one tenet of this principle is to communicate -- through listening and consulting, thereby increasing our understanding of what our customers need, what they like and dislike about our programs, and how we can serve them better overall. This principle says that HCFA will consult with our partners and beneficiaries about how our programs and policies should improve, instead of dictating such changes to them as has been done too often in the past. When changes are a result of legislative initiatives, HCFA will consult with partners and stakeholders on the range of implementation issues that need to be addressed.

- Educate rather than inundate -- Top rate customer service also means making sure that customers understand our programs and policies. Providing reams and reams of information is not enough -- and probably not effective. The "new" HCFA is committed to educating instead of inundating. This principle ensures that HCFA will educate our customers by developing effective educational techniques and disseminating information about how our programs operate rather than inundating them with information that is difficult to understand and doesn't speak to their needs.

- Innovate more than regulate -- HCFA's new and improved mission of customer service is driven by innovation more than regulation. This means that HCFA will rely upon innovation in program operations and administration more than regulation to foster improved customer service capabilities. For example, by streamlining Medicare claims processing and information exchange, the Medicare Transaction System will make electronic interaction with Medicare easier for providers and beneficiaries and will enable Medicare contractors to devote more time to customer service activities.

Accomplishments

HCFA's recent regulatory improvements include:

- In March, 1994, HCFA published a regulation that replaced the requirement for physicians to provide hospitals annually with a signed acknowledgment concerning penalties for misrepresenting certain information with a one-time signing requirement at the time a physician is initially granted hospital admitting privileges. One major medical association characterized this change as one that will alleviate the "hassle factor" for physicians and an important step toward restoring mutual trust between the Federal Government and the medical profession.

- HCFA is totally redesigning its system to pay claims for Medicare services. The development of the Medicare Transaction System (MTS) will increase control of program expenditures, and improve services to beneficiaries and providers. Final contracts for the analysis, design, development, testing, and implementation of the MTS were awarded January and March 1994.

  Presently providers must cope with 10 different claims processing systems operated by 77 insurance companies at 57 sites. HCFA has awarded a contract for the analysis, design, development, testing, and implementation of the MTS. This integrated, national system will replace the diverse existing systems and significantly simplify administrative operations for beneficiaries, providers, and the Medicare program.

- HCFA has re-invented the evaluation of Medicare contractors. The newly restructured Medicare contractor performance evaluation establishes Medicare beneficiaries and medical care providers as integral partners in the evaluation process. It allows for greater flexibility in evaluating Medicare contractor operations and performance. The new evaluation began October 1, 1994.

- Medicare and Medicaid inspections of most health care facilities (for example, nursing homes, hospitals, hospices, and ESRD facilities) are done using a flexible survey cycle. The frequency of a survey for any provider is a function of their past, and believed current, performance. Providers with poor compliance histories and/or current consumer complaints are surveyed more frequently than providers with good performance records.

- Obtaining Medicaid home and community-based services waivers was simplified in a rule published July 25, 1994. The final rule enables States to

offer a wide variety of home and community-based services as cost-effective alternatives to more expensive institutional care. Without this regulatory movement, joint State and Federal efforts to expand opportunities to provede cost-effective alternatives to insititutional care would have been frustrated. The regulatory provisions were worked out in collaboration with the States (through the National Governor's Association).

Regulatory Reform Recommendations

The following proposals are the major HCFA initiatives that have evolved from our commitment to the regulatory reform process. In some cases recommendations reflect actions based on collaborative efforts, including public consultation with industry groups, beneficiary organizations, and State associations and agencies. All of these projects were designed to cut unnecessary red tape and burdensome regulations. Most importantly, they demonstrate HCFA's customer-focus and responsiveness to the changing needs of all its customers and partners.

1. Nursing Home Regulation Enforcement: The monitoring and enforcing requirements for nursing homes participating in Medicare and Medicaid were revised and became effective July 1, 1995.

2. Physician Attestation: Eliminate the physician form required to certify the accuracy of all diagnosis and procedures before submission for payment by Medicare.

3. Clinical Laboratories Improvement Amendments: Make a series of significant changes that reduce burden and improve the entire CLIA system by recognizing technological advances, creating incentives for manufacturers, increasing access to a variety of tests, rewarding good performance, allowing private organizations that meet certain standards to accredit laboratories and permitting states to be exempted from CLIA requirements..

4. Outcome Performance Measures: Change current regulations that focus solely on requirements for measuring processes, rather than outcomes of care. Changes involve:

- Home Health Agency Conditions of Participation
- Medicare Hospital Conditions of Participation
- ESRD Facility Conditions of Coverage

- Rules for ESRD Facilities - A Pilot for Good Performers
- Elimination of Personnel Requirements for Excellent ESRD Facilities

X *5. Waive 50/50 Requirement For Medicare Managed Care Plans:* Change the current law that requires that all managed care plans providing service to Medicare beneficiaries have a commercial enrollment of at least 50 percent of total enrollment.

(4) *6. The HCFA-1500 Form:* All participating Federal Employee Health Benefit Plan carriers will use the HCFA-1500 form for physicians' and other practitioners' claims. The HCFA-1500 is used by physicians and others to submit claims for reimbursement of health care services under Medicare.

(5) *7. Annual Preadmission Screening and Annual Resident Review:* Eliminate the requirement that mentally ill and mentally retarded nursing home residents are assessed annually. The preadmission screening for these residents is retained.

(6) *8. Nurse Aide Training and Competency Evaluations:* Permits States to approve nurse aide training and competency evaluation programs offered in nursing homes.

HCFA INITIATIVES

1. Nursing Home Regulation Enforcement

Background: HCFA revised both the requirements nursing homes must meet to participate in Medicare and Medicaid and the rules for monitoring and enforcing requirements. The improved participation rules focus on resident quality of care and quality of life using outcome-based performance measures, where possible. These rules have improved conditions in nursing homes. For example, the use of physical restraints has been reduced 50 percent since 1987. More improvements in care and quality of life are possible.

Solution: The monitoring and enforcement rule, effective July 1, 1995, strikes the critical balance between strengthening quality standards in nursing homes to meet the health and quality of life needs of residents, and providing flexibility to apply remedies that fit specific problems at nursing facilities. Overall, the rule (1) links enforcement remedies to deficiencies; (2) motivates facilities to remain in compliance with Federal requirements that promote the quality of care and quality of life in nursing homes; (3) promotes survey and enforcement consistency; and, (4) avoids unnecessary burden on facilities through the use of an informal dispute resolution process.

Impact:

- 16,700 nursing homes are impacted by this rule.
- System is outcomes-oriented, not process oriented. Surveyors will focus on the direct care given to the resident, not on administrative processes.
- "Poor performers" are treated differently than "good performers." Facilities with good records are given the opportunity to correct their deficiencies and avoid remedies, while "poor performing" facilities (for example, those with a history of noncompliance, egregious deficiencies, or failure to implement a continuous quality improvement program), or those found to have an "immediate jeopardy," will be assessed immediate remedies, including civil money penalties.
- "Yo-Yo compliance" is discouraged. Facilities that routinely come into

compliance only long enough to be recertified, but that do not sustain compliance, can be sanctioned quickly.

- More remedies are available. This regulation recognizes that a single enforcement response is not appropriate for all deficiencies, and provides alternatives to existing remedies which are now only termination or denial of payment for new admissions.

- Remedies will fit specific problems. The regulation provides the flexibility to apply a remedy that fits the scope and severity, or level of "harm" that exists in each case.

- An informal dispute resolution is set forth in regulation. Providers are given an opportunity to dispute survey findings to the State or HCFA regional office. However, this informal review will not delay enforcement actions.

Implementation and Timeline: HCFA published a final enforcement rule November 10, 1994. It was effective July 1, 1995.

2. Physician Attestation

Background: Since the Medicare hospital inpatient prospective payment system (PPS) was implemented by HCFA in 1984, HCFA regulations have required physicians to sign an "attestation form" for each Medicare patient discharged from a hospital. The form certifies the accuracy of the diagnoses and procedures for each patient. This information is used to ensure that the correct coding is on the claim, the correct diagnosis-related group (DRG) can be assigned, and the proper Medicare payment can be made.

Feedback from physicians, hospitals, and intermediaries have told us that obtaining the physician's signature is burdensome and results in billing delays that hurt hospital cash flow and hinders service to the beneficiary. Peer Review Organization (PRO) review of attestations has resulted in fewer that a 0.01% denial rate of sampled claims. In addition, the improvement in hospital record keeping and coding sophistication make the hospitals the appropriate focus for combating fraud and abuse.

Proposed Solution: Eliminate the form requirement and instead hold hospitals responsible for the accuracy of their diagnoses and procedures. With improved technology and software coding capabilities, hospitals are more equipped than ever to combat billing fraud and abuse, the form's original purpose. This change, which can be implemented by regulation, will have the following benefits:

Impact:

- Reduces paperwork burden and "hassle" on physicians and hospitals.
- Decreases administrative costs for hospitals.
- 11 million forms will be eliminated.
- Almost 200,000 hours of physician time will be saved.
- Hospitals will have improved cash flow and reduced labor costs by approximately $22,500 per hospital per year.

Implementation and Timeline: HCFA will publish this final regulation September 1, 1995.

3. Clinical Laboratory Improvement Amendments

Background: The Clinical Laboratories Improvement Amendments (CLIA) of 1988 established baseline quality standards that ensure the accuracy, reliability, and timeliness of laboratory testing. These requirements are based on the complexity of the test performed, rather than where the test is performed. Compliance with the standards is determined through on-site inspection.

HCFA and the Centers for Disease Control and Prevention, which share responsibility for the CLIA program, continually review ways to reduce the burden and improve the entire CLIA system. A flexible survey system that employs data analysis to target good performers and allow for self-attestation and off-site review has already been initiated for certain laboratories. HCFA has reduced information requirements and eliminated unnecessary paperwork and has taken steps to reduce personnel requirements. HCFA also revised and streamlined the inspection process. Additional burden reductions are being undertaken that will virtually eliminate oversight for certain laboratories, establish performance standards in place of process requirements, and use information and education as a substitute for sanctions.

Proposed Solutions:

1. Waive the routine 2-year survey of users of "black box" technology, conducting surveys only if there are indications of problems or complaints. ("Black box" technology refers to simple and easy to use test systems that have demonstrated accuracy and precision through scientific studies.) We will develop and implement criteria for accurate and precise "black box" technology that will be followed to determine if the technology qualifies for waiver of the routine 2-year survey. A small number of surveys will be conducted to validate the criteria for determining "black box" technology and assure quality.

   Impact:

   - Creates incentives for manufacturers to develop more reliable testing equipment by stimulating demand for accurate and precise technological testing systems.

   - Reduces paperwork and costs for providers, especially for physician office laboratories, as well as costs of program management.

Implementation and Timeline: Proposed rules will be published September 1995.

2. Clarify and expand the waiver criteria and streamline the waiver process so that CLIA regulations can be waived for more tests. CLIA requirements will be waived for tests approved for home by the FDA -- that is, tests that do not require trained personnel.

Impact:

- Decreases burden, especially for physician office laboratories because of less regulatory oversight.

- Increases access to greater variety of tests. Physician office laboratories may expand the range of tests they perform without an increase in costs/burden.

- Creates incentives for manufacturers to develop more test systems that meet the clarified waiver criteria and criteria for approval for home use.

- Eliminates inspection fees for many of the 60,000 physician office and other small laboratories not now waived who decide to perform only tests from the expanded waiver category.

- Many additional laboratories will face lower inspection fees because, while they will continue to perform non-waived tests, many more tests will fall into the expanded waiver category.

Implementation and Timeline: Proposed regulations will be published in September 1995.

3. Use performance standards and require less frequent on-site inspections (surveys) of excellent performers. Approve private accrediting organizations for deemed status when their accreditation standards are as stringent as CLIA. Exempt laboratories from CLIA requirements when the State where they are located has requirements equal to or more stringent than CLIA's.

Impact:

- Reduces inspection burdens.

- Rewards good performers with fewer inspections. This is a positive incentive to improve performance.

- Approving organizations for deemed status offers laboratories oversight by peers.

- Approving States for CLIA exemption allows expanded role for States with strong licensure programs.

Implementation and Timeline: To date, notices to approve four accrediting organizations (College of American Pathologists, Joint Commission on Accreditation of Healthcare Organizations, Commission on Office Laboratory Accreditation, and the American Society of Histocompatability and Immunogenetics) and the State of Washington have been published. Notices for two additional accrediting organizations and one additional State are pending. Final rules to eliminate redundancies or unnecessary requirements for federal review and approval will be published in March 1996.

4. Use proficiency testing (PT) "failures" for education and as an outcome indicator in laboratory quality. (PT is testing samples of known values to assess the accuracy of a laboratory's results.) Sanctions (for example, loss of Medicare payment or loss of approval to do testing) are imposed only in cases of immediate jeopardy or when the laboratory has refused to correct the problem or has had repeated failures on proficiency testing.

Impact:

- Less intrusive than traditional regulation and oversight.

- Allows use of proficiency testing as an outcome measure to monitor laboratory performance, and provide laboratories with feedback on test quality and an incentive to improve performance.

- Minimizes the fear of sanctions in 60,000 non-waived laboratories.

Implementation and Timeline: A proposed rule will be published in March 1996.

4. Outcome Performance Measures

Background: Medicare, as a purchaser of health care, requires hospitals, Home Health Agencies (HHAs), and End-Stage Renal Disease (ESRD) facilities to meet health and safety requirements to participate in the Medicare program. Historically, these requirements measure "process" (procedural and administrative systems as proxies for quality health care) rather than "outcomes" (evaluations of actual patient care) and the adequacy of quality management programs.

HCFA is committed to changing current regulations that focus solely on requirements for measuring processes. The Agency realizes that not focusing on outcome measures results in several inherent problems. First, regulatory requirements vary by type of facility and provider even when the services provided in each facility are the same, creating inequities and inappropriate incentives. Second, without outcome measures, there is very little information available for consumers on the quality of care at a given facility. Third, by law, HHAs must be surveyed yearly—even though historical data show that this frequency is excessive for many HHAs and does not improve care.

HCFA is revising regulations for hospitals, home health agencies, and end stage renal disease facilities, that would address these issues and eliminate unnecessary process requirements and focus on the outcomes of care.

Proposed Solution: Eliminate unnecessary process requirements and instead develop outcome-based performance standards; collect and analyze patient care data needed for continuous quality improvement and performance evaluation; increase consistency of requirements across providers; and ask the customer to provide input on what the outcome measures should be, and to evaluate the services they received. We are seeking legislation to give us flexible survey cycles.

Impact:

- Eliminating unnecessary process requirements for compliance will reduce compliance and survey burdens and make it possible to focus on actual patient care.
- Educating the consumer will produce a strong, non-regulatory force to improve quality of care.
- Powerful data will be available to regulators and providers.

- Produces savings because providers are free to achieve high quality outcomes in the most cost-effective manner.

Outcome Performance Measures Initiatives

HCFA is currently involved in the following new initiatives that focus on the concept of "Outcomes Performance Measures" and the consensual approach to developing regulations.

Home Health Agency Conditions of Participation:

HCFA is developing revisions to the Medicare Home Health Agency (HHA) conditions of participation. The purpose of the revision is to place greater emphasis on patient outcomes while reducing the current emphasis on process requirements (e.g., elaborate professional qualifications and other "paperwork" requirements) and enhancing an HHA's flexibility in meeting patient needs. The Agency has actively involved home health beneficiaries, providers, physicians, professional organizations (American Association of Retired Persons, National Association for Home Care, American Federation of Home Health Agencies, American Medical Association, Visiting Nurses Association of America, American Academy of Home Care Physicians), States (State Survey and Medicaid Agencies), and intermediaries in order to receive input on developing revisions to the conditions of participation. A work group of HCFA staff and representatives of Medicare beneficiaries, home health providers, physicians, and State Survey Agencies will develop a Standard Core Assessment Instrument for use in home health care. The use of this tool is central to HCFA's efforts to place the emphasis of survey and enforcement on patient outcomes.

Implementation and Timeline: HCFA will publish a proposed rule in September, 1996.

Hospital Conditions of Participation:

HCFA is revising the current hospital conditions of participation to center on the patient, support a cross-functional approach to patient care, and focus on quality. In developing these revisions, HCFA has worked closely with organizations representing hospitals, practitioners, patients, and States and has already distributed informal pre-regulatory drafts to approximately 70 outside groups for

comment.

Implementation and Timeline: HCFA will publish a proposed rule in January, 1996.

End Stage Renal Disease (ESRD) Conditions of Coverage:

HCFA's ESRD Conditions of Coverage (COC) have not been comprehensively revised since their original implementation in the late 1970's. The current COC are primarily focused on process-oriented requirements, and do not provide adequate support for a modern survey system based on an outcome-oriented approach. Under the current regulation, facilities have a substantial paperwork burden. As a result, revised regulations must be issued to increase facility flexibility and to bring the ESRD COC up to current standards of practice in the ESRD community. The revised COC will address the outcome-oriented, patient-centered standards process where appropriate, reflect innovations in the dialysis and transplant community, and address new issues such as adequacy of dialysis to ensure that the Medicare beneficiary is receiving the most progressive quality of care possible. Thus, HCFA's emphasis will be on the total patient experience with dialysis, including patient functional well-being and continuous quality improvement (CQI). The revised regulations will include development of performance expectations for the facility that result in quality, comprehensive care for the dialysis patient.

Implementation and Timeline: HCFA will publish a proposed rule in March, 1996.

Rules for ESRD Facilities - A Pilot for Good Performers:

HCFA is conducting a pilot project to apply a different, less prescriptive set of rules to excellent ESRD facilities. Under the pilot project, an ESRD facility's performance will be measured using only three key patient care outcome indicators. First, these indicators will be used in place of the current certification standards, which are largely structure and process requirements. Second, the pilot project will focus on helping facility staff's use outcome measures in an ongoing way to improve the care provided to dialysis patients. Third, facilities that document sustained achievement in the outcome indicators over six consecutive months will be awarded a HCFA certificate of excellence.

The indicators measure the quality of hemodialysis in three areas critical to the health of the patient: adequate dialysis, control of anemia, and adequate water supply. They will be used by the facilities to monitor the condition of each dialysis patient and to achieve improvement in the patient's health status. For the pilot project, excellence will be identified through a process focused on the quality indicators. The process will look at whether facilities have an internal quality monitoring and monitoring system, whether the results of such monitoring are documented, and whether results are sustained. The facilities that qualify in this pilot will have established certain internal quality control mechanisms in order to participate.

Information about project results will be packaged in brochures and newsletters so that ESRD patients and non-participating ESRD facilities will be aware of the results. In this competitive industry, a successful project will stimulate many other providers to seek recognition as "EXCELLENT" facilities.

ESRD facilities will be notified of their eligibility to participate and participation will be voluntary. The pilot will be limited to facilities in the States of Colorado, Idaho, Montana, and
Washington.

Implementation and Timeline: Planning for this pilot is underway.

Elimination of Personnel Requirements:

HCFA is conducting a pilot project that will evaluate the impact of the elimination of Medicare personnel requirements for ESRD facilities. Currently, the Medicare conditions for coverage for ESRD facilities include fairly detailed specifications for several types of personnel employed in furnishing ESRD services to Medicare beneficiaries. For example, the medical director of the facility must be a physician, board eligible in internal medicine; the nurse in charge must have 12 months of clinical experience, with 6 months experience with ESRD patients; the social worker must be master level educated, etc. Over the years, HCFA has received comments from the industry both in favor of elimination of the personnel requirements and in favor of strengthening them. Those in favor of relaxing the requirements commonly cite the difficulty rural facilities can face in recruitment of personnel with the requisite experience. They believe that the job does not require the level of experience and education prescribed in order to perform adequately. Those in favor of maintaining personnel requirements cite the medical condition of ESRD patients as justification for the skills level requirements. They express concern that if the

personnel requirements are weakened or eliminated that ESRD facilities, most of which are proprietary entities, would hire less experienced and more inexpensive personnel to provide care that is of inferior quality.

The pilot project would be conducted in concert with another proposed project establishing new rules for historically good ESRD performers (see above) being conducted by HCFA's Seattle Regional Office. HCFA will collect information regarding the skills level of all personnel employed by those facilities participating in the project. Facilities would be informed that as part of the project, Medicare would not apply any of the personnel requirements contained in the conditions for coverage. At the end of the two-year project period, HCFA will recollect information regarding the education and experience level of all the facility's staff and evaluate the impact of the changes on predetermined measures of quality of care.

Implementation and Time line: Planning for this pilot is underway.

5. 50/50 Waiver for Medicare Managed Care

Background: Current law requires that all managed care plans providing services to Medicare beneficiaries have a commercial enrollment of at least 50 percent of total enrollment. The 50/50 requirement is intended to be a proxy of quality. It has the unintended consequence of making it less likely that managed care plans will contract to provide care in rural areas.

Proposed Solution: Under this legislative proposal, managed care plans that either are seeking Medicaid contracts under a State Medicaid managed care initiative, or are planning to operate as Medicare contractors in a predominantly rural area, would be eligible for a waiver of the 50/50 rule if they met certain quality-based requirements. These requirements would include a positive track record as a Medicare contractor, minimum commercial enrollment and the provision of encounter data on enrollees. This proposal is necessary to increase access to quality managed health care for Medicaid and Medicare beneficiaries who reside in rural areas.

Impact: This proposal would remove a barrier to HMOs located in rural areas. It will also improve access to care for Medicare and Medicaid beneficiaries.

Implementation and Timeline: The statute must be amended to make this change. Legislation will be proposed.

6. The HCFA-1500 Form

Background: The HCFA-1500 form is currently used by physicians, other practitioners, and DME suppliers to submit claims for Medicare reimbursement of health care services. HCFA-1500 is also used by many other insurers for claims submission. Although many Federal programs require the use of the HCFA-1500, use of the form is not required by the Federal Health Benefit plan (FEHBP). In addition, instructions for the form vary across programs.

Proposed Solution: The Office of Personnel Management (OPM) will require participating carriers to notify physicians that they accept the HCFA-1500 form for claims filed under FEHBP.

Impact: Physicians will be able to use one form to submit claims for services provided to many patients.

Implementation and Time frame: OPM will use the HCFA-1500 beginning January, 1996.

7. Preadmission Screening and Annual Resident Review (PASARR) of Mentally Ill and Mentally Retarded Residents

Background: Nursing homes under Mediacare and Medicaid are currently required by law to conduct an initial assessment of each resident within14 days of admission, with a reassessment whenever a significant change in condition occurs but in any event at least once a year. In addition, there is a statutory requirement that for persons with serious mental illness or mental retardation entering a nursing home the State is required to conduct: (1) a preadmission screening to assure that the individual is being appropriately placed in a nursing home, and (2) an annual reassessment to assure that the patient continues to be appropriately diagnosed and treated.

Proposed Solution: Legislation would be proposed to eliminate the duplicate annual assessment. Resident assessments and reassessments required under the general nursing home requirements are entirely adequate to assure that residents continuing needs are properly assessed and met. Preadmission screening, which appropriately deters inappropriate admissions, would continue.

Impact: By eliminating the redundant annual PASARR reassessment, costly duplication of effort by States would be reduced and nursing facilities would be relieved intrusive annual inspections.

Implementation and Timeline: Legislation will be proposed.

8. Nurse Aide Training and Competency Evaluations

Background: To assure quality of care in nursing homes, current law prohibits nursing homes from using nurse aides that have not successfully completed a training or competency evaluation program. The statute requires the Secretary to establish requirements for the approval of nurse aide training and competency programs. The law further forces States to prohibit, for a period of two years, nurse aide training and competency evaluation programs operated by or in nursing homes that were subject to an extended survey or partial extended survey or certain other sanctions. (Extended or partial extended surveys are conducted as more intensive follow-up investigations after a routine survey has demonstrated that a facility is furnishing substandard care.)

When a facility's program has been disapproved, the facility may not even be the site of an aide program conducted by others during the time that the two-year penalty is imposed. The prohibition on approval of nurse aide training and competency evaluation programs causes a special problem for rural nursing homes where a community college or other training facility may be inaccessible to nurse aides. Rural facilities can face a serious shortage of trained and competent staff due to the expense and inconvenience of sending prospective aides to remote locations. Alternative training programs may not be available.

Proposed Solution: Specify that a State could choose to approve a nurse aide training and competency evaluation program offered in (but not by) a nursing home subject to an extended or partial extended survey or certain other sanctions if the State determines that there is no other nurse aide training and competency evaluation program offered within a viable distance. States would be required to provide ongoing oversight of these programs in the interest of patient health and safety.

Impact: This proposal would safeguard the availability of nursing homes which might otherwise stop participation in the Medicare and Medicaid programs as a result of losing a training programs' approval. It would also make it easier for nurse aides to obtain the training they need to provide quality services to our beneficiaries.

Implementation and Timeline: The statute must be amended to make this change. Proposed legislation is under development.

Conclusion

Under President Clinton's leadership, HCFA has made communication, cooperation, and partnership the guiding principles of the regulatory process, replacing the adversarial environment that often existed in the past. At a time when the American health care system is undergoing dramatic changes, HCFA is committed to "putting the federal government's customers -- the American people -- first". We are pleased to report that the initiatives described in this report represent just the beginning phases of HCFA's ongoing support of the National Performance Review efforts.

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

30-Jun-1995 02:32pm

TO: (See Below)

FROM: Allison H. Eydt
Office of Mgmt and Budget, OIRA

SUBJECT: Stark I Revised Preamble Language

HHS faxed me materials addressed to you reflecting revised preamble language for the Stark I regulation. These materials are a follow-up to your Stark conversations with Administrator Vladeck last Friday.

The preamble language continues to argue that HCFA does not have administrative discretion to create a shared office laboratory exception. In particular, the preamble states, "We believe that this provision (section 1877(b)(4)) says and means 'no potential for abuse.' The statute does not say that HCFA can create new exceptions whenever it determines that there are potential abuses, but that these are outweighed by policy concerns such as the flexibility an exception will give to the provider community or to patients."

I continue to question HCFA's rigid interpretation. Such an interpretation renders the flexibility provided the Secretary to offer exceptions under section 1877 (b)(4) (when the exception "does not pose a risk of program or patient abuse") as useless and undeserving of delicate underlying Congressional negotiations.

Instead of an administrative exception, HCFA states, "we believe that it is up to Congress to draw the line on what it would consider to be an acceptable amount of risk and any criteria necessary to minimize that risk." HCFA then offers a detailed legislative exception that is comparable to the existing in-office ancillary services exception. The proposed exception includes two other important features, however. It is limited to a laboratory that "is shared by five or fewer physicians ("shared laboratory physicians")" and "the profits of the shared laboratory cannot be shared based directly on the volume or value of referrals." These additional provisions are designed to discourage flagrant overutilization.

I believe that this exception has great potential and appeal, particularly if HCFA would adopt it administratively. Supporting

this, John Morrall came up with an interesting economic

perspective. One could argue that HCFA legally can adopt this provision administratively because it may REDUCE NET PROGRAM ABUSES resulting from existing legislative Stark provisions. Assuming that physicians do not shut down laboratory operations all together or refer out, in the absence of such a provision, physicians may have the incentive to spin off into single physician office labs where the referral/profit relationship is guaranteed to be one-for-one. Five physician office laboratories operating under these incentives logically would create more overutilization and program abuse than one laboratory of five physicians that "cannot share profits based directly on the volume or value of referrals." Therefore, it would be fiscally irresponsible for HCFA to ignore this administrative opportunity to mitigate the net impact of program abuses resulting from existing legislated exceptions.

I shared this analysis with RMO staff. They find it interesting, but not entirely compelling in the absence of strong empirical evidence.

HCFA is waiting for feedback from you. Despite, the RMO staff's skepticism, I recommend that we share this argument with HCFA, and continue to press for adoption of an administrative exception (perhaps one identical to their legislative proposal.)

In case you are interested, more ideas pertaining to volume threshholds are coming. . .

Distribution:

TO: Sally Katzen

CC: Phyllis E. Kaiser-Dark
CC: James B. MacRae Jr.
CC: John F. Morrall, III
CC: Daniel J. Chenok
CC: Joseph F. Lackey, Jr.
CC: Mary W. Poag
CC: Jennifer L. Klein

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

OFFICE OF INFORMATION AND REGULATORY AFFAIRS

FAX TRANSMITTAL

FAX: (202) 395-6974

DATE: 6/29/95

TO: Jen Klein

FROM: Allison Eydt

****

TOTAL NUMBER OF PAGES (INCLUDING TRANSMITTAL SHEET): 6 pgs

RECIPIENT'S FAX NO: 6-2878

RECIPIENT'S TELEPHONE NO:

COMMENTS:

You may want to use this for the roll out or even push for the exception in the rule, not legislation. Call if you have questions.

NOTE: IF YOU DO NOT RECEIVE ALL OF THE PAGES, PLEASE CALL AS SOON AS POSSIBLE.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

June 23, 1995

NOTE TO SALLY KATZEN, OMB

SUBJECT: Revised Preamble Language for Stark I Regulation

As we agreed, HCFA has drafted some language for the Preamble to the Stark regulation that lays out fully the reasons why a shared laboratory exception cannot be established through regulations. It also contains specific legislative recommendations for establishing a shared laboratory exception.

The attached language was, as you can see, drafted by OGC. The language was drafted for the Federal Register, not OMB, so it contains all the reasons why we are not establishing a shared laboratory exception -- including references to intent and legislative history that would not bind us if we were able successfully to craft an exception under current law.

We're certainly willing to modify the language to delete any offending sections, but we believe generally that the final rule should contain as comprehensive a defense of the position it takes as it is possible to draft.

Please call if you want to discuss this or FAX a mark-up.

Thank you.

Bruce C. Vladeck

MEMORANDUM

TO : Tom Hoyer
BPD

FROM : Myra K. Erhardt
Attorney

SUBJECT: Revision of the preamble for BPD-674-FC to reflect HCFA's policy on shared labs

As you requested, we have revised as follows the section of the preamble for BPD-674-FC which discusses shared laboratories:

1. The response on E16 should be revised as follows:

Response: We received a large number of comments addressing the shared laboratory issue and many detailed suggestions for designing an exception for shared laboratories. However, our legal authority to create an exception for shared laboratories is extremely limited.

The statute contains a long list of exceptions to the broad general prohibition on referrals. Many, if not all, of these exceptions, appear to reflect Congress' weighing and balancing of the need it perceived to curtail abusive financial arrangements while not interfering excessively in the effective delivery of health care services. Congress constructed these exceptions to reflect practical decisions it made after talking at length to the health care community. For example, Congress chose to exempt from the prohibition any physician who has an ownership or investment interest in an entity that provides services in a rural area or in a hospital in Puerto Rico. We are aware of no evidence to support the assumption that all such arrangements are immune from abuse; however Congress, for policy reasons, chose to provide a blanket exception for all of these relationships.

Similarly, Congress chose to except most in-office ancillary services provided by a solo practitioner or group practice physician in his or her own offices.

The legislative history for § 1877 does not indicate that Congress excepted these services because it believed they were immune from abuse. In fact, there are studies showing that physicians can and do over-utilize and overcharge for services they provide in their own offices. Congress apparently provided this exception because it did not wish to intrude into the internal operations of an individual practice.

Congress demonstrated its awareness of the shared laboratory issue by considering a shared laboratory exception as part of its OBRA '93 amendments to § 1877. Congress specifically chose not to create a blanket exception in the law for all shared laboratories or for any particular category of shared laboratories. The legislative history makes it clear that Congress considered a limited shared laboratory exception but chose not to enact it. The conference report for OBRA '93 describes the House Energy and Commerce Committee's proposal for a shared laboratory exception, but specifically points out that this provision was not included in the conference agreement (H.R. Rep. No. 213, 103d Cong., 1st Sess. 809-810 (1993)). In addition, Congress very deliberately established certain standards in § 1877(h)(4) as those necessary for an association of physicians to qualify as a group practice in order to share a laboratory under the in-office ancillary services exception. Congress retained these standards in OBRA '93 and in fact added further requirements.

Although we understand that there may be practical reasons for a shared laboratory exception, we do not believe that the statute gives HCFA the authority to engage in the same type of balancing which Congress undertook in enacting (and amending) § 1877. HCFA does not have the authority to radically revise or alter any of the provisions in § 1877. For example, HCFA does not have the authority to expand the in-office exception to include shared laboratories. HCFA instead has only the independent authority under § 1877(b)(4) to create exceptions for additional financial relationships, but only when it determines that an exception "does not pose a risk of program or patient abuse."

We believe that this provision says and means "no potential for abuse." The statute does not say that HCFA can create new exceptions whenever it determines that there are potential abuses, but that these are outweighed by policy concerns such as the flexibility

an exception will give to the provider community or to patients. The legislative history for the original self-referral prohibition reveals that Congress considered giving the Secretary the authority to create additional case-by-case exceptions with respect to ownership or investment interests. The Secretary could provide an individual exception if an entity demonstrated to the Secretary's satisfaction that the items and services provided by the entity would otherwise be unavailable to patients in the area, the items and services provided by the entity would be more convenient to patients based upon travel time, or the items or services provided by the entity would be supplied at substantially lower cost. This authority was never enacted. H. Conf. Rep. 386, 101st Cong., 1st Sess. 847-848 (1989).

We believe that the "does not pose a risk of program or patient abuse" standard is a very difficult one to meet and must be based on evidence that the exception could not be used to circumvent the purposes of the law. However, by its very nature, a shared laboratory facility will be one in which the physician-owners will share in the profits; each additional referral will likely increase the income of the facility and the share of each investor.

Commenters advocating a shared laboratory exception have suggested a variety of standards that a shared laboratory would have to meet. A number of commenters suggested that a shared laboratory exception should, among other things, limit the size of the laboratory, its location, or the number of physicians who can invest in it. However, we are aware of no evidence that the size or location of any shared investment either increases or decreases the incentive for investors to make referrals to it. We also have no evidence that any of the other criteria suggested by the commenters would prevent abuse.

Even assuming we have the latitude to interpret "does not pose a risk of program or patient abuse" to mean only a significant or meaningful amount of risk, any attempts we might make to draw a line between acceptable and unacceptable amounts of risk would be purely arbitrary. Should anyone be aware of data that demonstrates that certain criteria will prevent or greatly reduce the potential abuse of patients or of the Medicare program, we would be very interested in receiving it.

In light of the many practical concerns commenters have raised about shared laboratories, we believe that Congress should "weigh and balance" the issue and consider again whether to establish a shared laboratory exception. We believe that it is up to Congress to draw the line on what it would consider to be an acceptable amount of risk and any criteria necessary to minimize that risk. We have the following suggestions on how Congress might wish to design a shared laboratory exception for small laboratory facilities which serve a limited number of physicians who are all located in one building. Our suggestions are based not on assumptions about what criteria would prevent the risk of abuse. Instead, we have attempted to design an exception which addresses many of the specific problems raised by the commenters, and is comparable in many ways to the in-office ancillary services exception.

The exception would apply to shared laboratory services that are furnished:

(1) by a laboratory that-

(a) is shared by five or fewer physicians ("shared laboratory physicians"); and

(b) is located in the same building in which all the shared laboratory physicians furnish physician services unrelated to the furnishing of laboratory services;

(2) personally by a shared laboratory physician or by an individual who is directly supervised by a shared laboratory physician; and

(3) to a patient of a shared laboratory physician who received physician services unrelated to the laboratory services in the building in which the shared laboratory is located.

The shared laboratory cannot require that the shared laboratory physicians maintain a volume of referrals to the laboratory. The profits of the shared laboratory cannot be shared based directly on the volume or value of referrals.

1. On page E19, lines 15-16 should read: "In any case, as explained above, we do not believe that we have the authority to establish a separate exception for shared laboratories."

Please let us know if we may be of further assistance.

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

06-Jul-1995 12:26pm

TO: (See Below)

FROM: Daniel J. Chenok
Office of Mgmt and Budget, OIRA

SUBJECT: HCFA Roll-Out Meeting and CLIA/Starke issue

Hope you're having a great time!

On the whole, yesterday's HCFA Roll-out event meeting was productive and HCFA agreed to make most of the changes that we advocated. This note summarizes the status of the CLIA exceptions that remain outstanding (shared facilities and testing); the changes that HCFA agreed to in the book; and the event logistics FYI. Please try and at least read the CLIA/STARK section ASAP. Thanks.

CLIA/STARKE

This is the only issue that you may need to make a policy call on today. Bruce Vladek would like to speak with you about whether to include the shared facilities exception as part of the roll-out. His inclination is to leave it out at this time, since the sticing remains whether to propose the policy in regulation or through statute. We still believe and strongly recommend that this exception be achieved through regulation, and that we not let event timing dictate an agreement that may need further discussion. Vladek seemed willing to listen, but his attorneys have deemed that sufficient flexibility does not exist to allow a regulatory fix.

Jennifer Klein with the DPC would like to include this issue, but will defer to our judgment to leave it out if necessary. Elaine Kamarck wanted to know if we could at least include a placeholder. One possibility that Allison and I discussed would be to announce the policy as framed in HCFA's legislative proposal that we all agree on, excepting shared labs with 5 or fewer doctors; and to explicitly indicate that the Administration is exploring the most effective and responsible avenue for implementation, legislative or regulatory.

Note that the Health RMO position remains unresolved. RMO staff oppose an exception, while Nancy-Ann appears more sympathetic. Jen Klein is calling her for a more dfeinitive

position before you call Bruce.

CHANGES TO THE BOOK/ROLL-OUT

1. HCFA is adding a new initiative to the book, a legislative proposal to allow nurse aide training in rural areas by "substandard" facilities. Current rules do not allow in-house training by some facilities, which means no training in many rural areas since other sources are not available. This legislative proposal to give relief in rural areas builds on prior regulatory changes made in the nursing home enforcement rule.

2. HCFA will discuss exploration of a legislative proposal on exempting "black box" technologies from CLIA oversight as a more effective counter to current Congressional proposals. We will see what language they come back with, and try to ensure that it is sufficiently strong (Elaine pushed this as well).

3. HCFA agreed to expand the end-stage renal disease pilot under "performance measures" to indicate that this is a model that they will expand to other areas as a way to reward good performers. At our urging, they will also add a quid pro quo of more flexible enforcement and regulatory relief, in addition to simply providing "certificates of excellence".

4. HCFA will add realistic time frames in this Administration for most proposals, and will add estimates of burden reduction where appropriate.

5. On physician attestation, HCFA will announce a final rule without proposal as we have advocated, by this September.

EVENT LOGISTICS

As of now, the event will be called "Reinventing Health Care Regulation", and will be in Room 450 OEOB at 12:30 on Tuesday. Various doctor's, nursing home, and consumer groups will attend, as will congressional staff and perhaps Dingell, Stark and Mikulski among others.

Congressional staff and labor unions will receive oral briefings prior to the event. Just before, Vladek and the First Lady will meet with the doctors' groups.

The First Lady will open the event, and introduce Dr. Steve Gleason who will discuss the wondrous burden reduction of physician attestation reform. The VP will then put this in the context of other regulatory events, followed by (potentially) remarks from the President.

You and Vladek are then expected to attend a briefing in the press room. You can also expect a call from Ron Faunier (sp?)

from AP on Monday night, who will prepare the wire story for Tuesday release.

Distribution:

TO: Sally Katzen

CC: Allison H. Eydt
CC: John F. Morrall, III
CC: James B. MacRae Jr.
CC: Mary W. Poag
CC: Jennifer L. Klein
CC: Phyllis E. Kaiser-Dark

Health Care
Event - ~~UHCR~~ Reg. Reform

Order:

First Lady - Gleason - FL - VPOTUS

Health care imp. to us. While health care reform, VPs Reinv. Gov. working at same time.

- Need simplicity / reduce burdens

FL & Steve set up problem
↳ Do attestation

- REGO & HCR perfect marriage
- Last year - eliminated paper

→ Get acknowledgements from Bruce's office
→ FL briefing -- talk to Brenda
→ Finish remarks

Warman
Pryor
Wyden
Stark
Dingell
Mikulski

} Bruce to do briefing
Janet to talk to Debbie Chang

Press

- George Anders --
  10 minute w/ VP & Bruce -- ask Lorraine to sign off
- Ron Fournier -- to be called for AP -- Bruce would need to be available ~~evening~~ -- Sally would get call

URGENT FAX

RUSH TO: Jennifer Klein, DPC [v: 456-2599]

FAX: 456-2878

FROM: Robert A. KNISELY

PAGES (INCLUDING THIS COVER): 3

Jennifer Boulanger, Molly Poag, Jennifer Klein: here's my first chop at the HCFA paper. See you on Wednesday afternoon. KNiZ

Tuesday, July 4, 1995

From the Desk of **Robert A. Knisely**

To: Jennifer Boulanger, HCFA re: Reinventing HFCA Regulations

First, I want you to know that I can see you've done a heck of a lot of work in these 18 pages so far. We're not home yet, but I can tell it's possible to be done before the 11th, and possible without spending all weekend NEXT weekend on final edits and policy dust ups. Congratulations!

I hope you found a copy of the FDA Reinventing Regulations report. Easier to follow.

I think that the audience is largely specialist, but occasionally generalist (we'd like to think so, anyway). Therefore, a quick look for really specialized language (ie. "deemed status") would be worthwhile. If we explain it once we're home free. I've made a quick start, which we can discuss tomorrow afternoon.

✓ Needless to say, we will need dates and form for all "deliverables," even deliverables to the Federal Register. That is, we must say that we will have an NPRM published in the Federal Register by September 30, 1995 (or whatever). The dates can become a sticking point. Please start picking some dates, and not too far in the future.

Also, please be aggressive in your use of the APA. You can expect some "cover" from OIRA here. Can we do any final rules? Perhaps the removal of physicians' attestation? Can we avoid the use of the ANPRM anywhere, since no one will think we're serious?

Already asked

I am hoping that the promised "BACKGROUND" section will include a good list of previous accomplishments of this Administration. We should have a separate section on these, even if some of the material is repeated later.

While we haven't done Executive Summaries for the previous reports, an introductory paragraph is still needed -- I hope that's in Background as well.

✓ You may have a little too much about reinventing HCFA; we'll see what others say.

Most of the rest of my comments are querulous, or "puppy to small dog" changes:

I like to sprinkle Americans and America throughout; I won't give patriotism away without a fight!

✓ We need to look carefully at the order in which you list impacts, for maximum advantage.

Page 1: Medigap is unexplained. Do you mean insurance carriers?

✓ Page 2: Don't we need to say health care providers once? Gotta say kidney along with renal, once.

The paragraph starting "HCFA," could be recast as goals, except that it's placed before goals.

Page 4: I think that "innovate more than regulate" requires more explanation. Don't you need to

Deputy Director, Bureau of Transportation Statistics
Room 2104, U. S. Department of Transportation, 400 Seventh Street SW, Washington, DC 20590
Voice: 202-366-DATA, Fax: 202-366-3640 (backup fax: 703-757-0293), & Internet: knz@bts.gov

Date: 07/04/1995
Time: 2:59 PM

From the Desk of **Robert A. Knisely**

reduce as well as revise Nursing Home Regulation's requirements? Don't youwant to "eliminate the requirement that physicians certify" rather than eliminate the form? Need some better language than "series of significant changes."

Page 5: HCFA 1500: Can you say that participating carriers must accept the HCFA 1500 w/o addenda? And you gotta say HOW you'll modify the annual requirement for RRRMIMRR.

Page 6: Needs some examples here. I can't tell what in fact you propose to do.

Page 8: HCFA and CDCP "have taken significant actions" -- share them with us, here and (I hope) in the Adminstration Accomplishments section.

Page 9: What states have more stringent requirements than CLIA?

Page 11: Re: process requirements for surveying HHAs annually; are you proposing legislation to make this every two years?

Page 14: Can you get your Good Performers from this pilot effort to help my mentoring others? By getting their good works written up? By being good "benchmarks"? Both EPA and OSHA are doing exciting things with their outstanding performers.

Page 15: Is waiving the 50% commercial requirement for managed care only a problem in rural areas? Don't center cities provide the same challenge?

Page 16: Must commit to getting some sort of result out of OPM by a date certain.

Page 17: I don't understand this. Are there two levels of review now, one "semi official?" I'd like to hear this one again. On its face, I don't like it.

Page 18: Can you talk a little about how these changes fit into a larger, more long term effort at re-regulation or reinvention at HCFA? That would be great!

See you tomorrow afternoon!

Deputy Director, Bureau of Transportation Statistics
Room 2104, U. S. Department of Transportation, 400 Seventh Street SW, Washington, DC 20590
Voice: 202-366-DATA, Fax: 202-366-3640 (backup fax: 703-757-0293), & Internet: kruz@bts.gov

Date: 07/04/1995
Time: 2:59 PM

ahca
American Health Care Association 1201 L Street, NW, Washington, DC 20005-4014
FAX: 202-842-3860
Writer's Telephone: 202/898-2828

June 9, 1995

Ms. Jennifer Klein
Special Assistant to the
President for Domestic Policy
2nd Floor, West Wing
The White House
Washington, DC 20500

Dear Ms. ~~Klein~~ Jennifer:

Attached please find the letter which I sent to Bruce Vladeck. I wanted to convey my thanks for assisting us in ensuring that these issues that are critical to the industry are successfully resolved. To that end, I would ask that at the very least, the PASARR and Nurse Aide Training issues be included in the Vice President's regulatory relief package. We will shortly be contacting you to discuss appropriate next steps that we need to take to ensure that this happens.

I believe that by including these two key provisions in the regulatory relief efforts, we will not only resolve key problematic concerns but will also show the over 16,000 long term care providers, the commitment by the Administration to provide regulatory relief to the provider community.

Likewise, I also believe that it is crucial that both the White House and the long term care industry continue to coordinate efforts and work together to oppose <u>any</u> and <u>all</u> attempts by Congress to block-grant Medicaid funds to the states. Although AHCA has already shared with you the efforts that we have undertaken in this regard, I would urge you to continue to keep us apprised of the efforts by the White House. Please do not hesitate to contact us and include us in your efforts.

Again, thank you for your assistance and we look forward to working with you on both these and other activities.

Sincerely,

Paul R. Willging, Ph.D.
Executive Vice President

G:\reg\je\9585

AHCA 6/7

PASSAR

- agreement on annual PASSAR - Do in reg. review
- need to look at initial more
  - look at duplication of residency assessment functions

Need joint legislative proposal - or they have proposal - we support some.

- logs of auth. to provide training in rural facilities
  - maybe if you can attribute substandard care to personel, would do limits on training
- deemed status
  - fight between AHA and JCAHO

2 components of care

- clinical + ADL
- payment rate ought to be the same whether indiv. is in hospital, institution, home

→ Willing to do a demonstration on 3-day subacute e.g. bed sores

→ Work group to come up w/ demo to be implemented early next year. OBD Barbara Cooper to head it up.

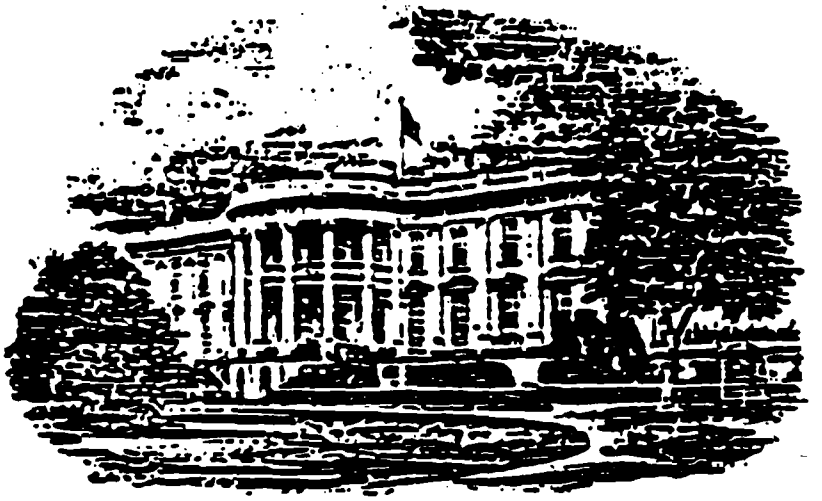
→ Going by Jan. 1

[Lewin study]

DATE: _____
TIME: _____

THE WHITE HOUSE

WASHINGTON



FAX COVER SHEET

TO: Steve Gleason

Bob Waters

PHONE: (___) _____

FAX: (___) 202-857-6395
515-~~222-7257~~
247-4259

FROM: J. Klein

PHONE: (202) 456-2599

PAGES FOLLOWING COVER SHEET: _____

6/30/95

FAX TO: Elaine Kamark
Bob Knisely
Doug Farbrother
Jennifer Klein
Sally Katzen
Molly Poag
Allison Eydt

Attached is HCFA's first draft of the Reinventing HCFA Regulations document. We are looking for the perfect quotation from President Clinton to open the report. The introduction section is being drafted and we will have that Wednesday. In addition, we will be adding additional material in the "HCFA Initiatives" section (mostly the "timeline" information).

Please give me your comments, as soon as you can. My number is 690-8502. Thank you.

Jennifer Boulanger

cc: Claudia Cooley
Jackie White