HCFA ADMINISTRATIVE STREAMLINING

December 14, 1994

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Communication with Medicare Beneficiaries

Issue: The Medicare program is increasingly complex and confusing. It is very important that we maintain good communication with our primary customers, the beneficiaries, so as to mitigate any confusion about the program.

Discussion: HCFA is implementing a number of initiatives towards improving communications with our primary customer, the beneficiary. In the Medicare program, the following activities are underway in terms of planning, pilot testing, or implementation:

- A combined Part A/Part B Medicare Summary Notice which will consolidate into a single, easy-to-read, monthly statement of all of a beneficiary's claims activity for the month. We will be eliminating the multiple forms that Medicare intermediaries and carriers currently use.

- The Medicare Summary Notice will allow the beneficiary to more easily request a review of their Medicare determination rather than the current process of making a separate request.

- The physician can be a patient advocate and we want to promote this important beneficiary service. Consequently, we are exploring the release of beneficiary claims data (the Explanation of Your Medicare Part B Benefits (EOMB)) to physicians who do not accept Medicare assignment (those that accept assignment already get this information).

- Recognizing diversity in the Medicare program is important to our communication efforts, we will be expanding the use of Spanish EOMBs and testing their success at effectively informing Hispanic beneficiaries.

Though these are just some of our communication ideas, HCFA is continually seeking and implementing other improvements to our communication vehicles with beneficiaries. Many of these ideas are provided to us by beneficiaries.

Status:

o Combined EOMB Notice. In December 1994, HCFA will be developing prototype notices. In February 1995, HCFA will be using beneficiary focus groups to gain feedback on the prototypes. The implementation target date is October 1995.

- Releasing EOMB Information to Non-Assignment Physicians. Release of this information was pilot tested in two regions, Kansas City and New York. The pilots were successfully completed in July 1994 and HCFA is planning for nationwide implementation.

- Spanish EOMB. Spanish EOMB's will be pilot tested in Florida beginning in April 1995.

Budget Impact: Each of these proposals has minimal budget impact.

Eliminate Fraud and Abuse

Issue: As a major payer of health care services in the country, the Medicare and Medicaid programs are natural targets for those wishing to gain financial rewards through fraudulent and abusive activities.

Discussion:

- Detection.

  We have consolidated payment of durable medical equipment (DME) into four carriers in order to enable us to focus claims review on this problem area. One of the four has responsibility for analyzing patterns within all DME claims to highlight problem areas.

  Working with carriers and intermediaries, we are developing advanced computer systems to detect fraudulent patterns of billing in all types of claims. This will enable us to intervene early when problems are suspected.

  In problem areas such as South Florida, we are combining Medicare claims with those from Medicaid to provide a more robust data base on which to detect unusual patterns. We plan to expand to include private claims with cooperation of several existing carriers.

  We are undertaking an education program to inform employees and beneficiaries of their responsibility to report suspicious practices.

  State surveyors who visit home health agencies and nursing homes will be trained to detect and report evidence of fraud. They will also be provided with information from claims analysis which indicates quality problems.

  The Medicare Transaction System (MTS), a uniform, national system for processing Medicare claims, will replace the diverse existing systems and provide HCFA with improved capability for identifying fraud.

- Prevention and Enforcement.

  We have initiated stricter standards for suppliers under Medicare and Medicaid and are working with States to trace repeat offenders who create new organizations in order to continue in the program.

  We are developing methods to ensure that both suppliers and providers who have engaged in fraudulent activities will not be able to move to another state and resume practice.

We are actively coordinating the enforcement activities of carrier fraud units, HCFA staff, the Office of the Inspector General and the Department of Justice in areas where high rates of fraud are suspected.

Status: These programs are all ongoing. GTE was awarded the design contract for the MTS in January 1994. HCFA plans to begin implementation in 1997.

Budget Impact: Significant savings are expected. Each additional dollar spent on payment safeguards activities, including fraud and abuse activities, would result in at least eight dollars of savings to the Medicare Trust Funds. The Department and HCFA continue to work to establish a secure source of funding for this important type of investment in program integrity.

Billing and Payment Improvements

Issue: Providers are increasingly frustrated with the perceived administrative burden and complexity of Medicare's billing procedures.

Discussion: HCFA has undertaken several actions under current law to streamline our billing and payment procedures. In addition, we are considering some legislative proposals as part of the 1996 budget and legislative process.

- Eliminating Pre-Billing Attestation Requirement.

  HCFA is eliminating pre-billing requirements for attestation by physicians of diagnoses and major procedures performed in the hospital. This will lessen the administrative burden on physicians who provide services to Medicare beneficiaries.

- Providing Uniform Identification Numbers to all Providers.

  HCFA is leading an effort involving other Federal payers of health services, including the Department of Veterans' Affairs, the Department of Defense, and State Medicaid agencies to provide unique provider identification numbers to all providers of government health services. Having uniform provider numbers for all government health programs will make it easier for physicians to complete billing forms.

- Simplifying the "Important Message from Medicare".

  HCFA plans to simplify the content of this message and to simplify the way hospitals distribute it.

Status: Work is underway on all three administrative actions. We expect to begin assigning new provider numbers by the end of 1996, before implementation of MTS.

Budget Impact: Minimal budget impact.

Medicare Transaction System

Issue: At present, Medicare and its providers must cope with 14 different claims processing systems operated by 79 insurance companies at 62 sites. Information flow from Medicare to providers, and vice versa, is unnecessarily slow, complex, and costly.

Discussion: HCFA has awarded a contract for the development, testing, and implementation of a new Medicare Transaction System (MTS). This uniform, national system for processing Medicare claims will replace the diverse existing systems and significantly simplify administrative operations for beneficiaries, providers, and Medicare. Implementation of the MTS will begin in 1997. Benefits that will flow from the new system include:

- Improved service for beneficiaries
- Improved service for providers
- Improved management of program expenditures
- Greater uniformity in coverage and payment decisions
- Enhanced capability to identify fraud
- Improved coordination of benefits

While MTS is being developed for the Medicare program, we acknowledge that MTS will have implications well beyond Medicare. MTS will well shape the environment for information transaction in Medicaid, public health, other government programs, and private industry. In the development of MTS, we are being sensitive to the needs of all industry participants, and are working to ensure that providers and payers are not caught between incompatible systems. HHS has moved to set up a steering committee to coordinate information policy within HHS and to ensure ongoing coordination with the private sector as data systems for HCFA and the Public Health Service are integrated and streamlined.

Status: GTE was awarded the design contract for the MTS in January 1994. HCFA plans to begin implementation in 1997.

Budget Impact: Without MTS, HCFA would have difficulty managing claims processing in an era of shrinking administrative budgets. By enhancing HCFA's ability to detect and prevent fraud, MTS will protect the integrity of the Medicare Trust Funds.

Changes Affecting Providers

Issue: The Medicare program has many administrative requirements that often burden and constrain providers.

Discussion:

- Facility Conditions.

  We are revising the conditions of participation for hospitals, end stage renal disease facilities, and home health agencies to make them more easily understandable, outcomes-based, and less process-oriented.

- HMO Organizational Structure and Services (OMC-007-F).

  This regulation will provide organizations which operate HMOs that are federally qualified under title XIII of the Public Health Service Act with greater flexibility in operating other health benefit plans. It would also authorize, with certain limitations, federally qualified HMOs to offer out-of-plan physician services and require a reasonable deductible for those services. Further, this regulation would permit the HMO to use assets of the parent organization to meet fiscal soundness and insolvency protection requirements.

Status: The hospital and the ESRD revisions are in the developmental stage. The Notice of Proposed Rulemaking for the home health agency conditions of participation is expected to be published in November 1995. The HMO final rule is scheduled to be published in 1995.

Budget Impact: No budget impact.

Transforming Medicare Peer Review

Issue: HCFA, through contractor Peer Review Organizations and ESRD Networks (hereafter referred to as Quality Improvement Programs (QIPs)), has historically monitored quality through a detection program. This was accomplished primarily through the intensive review of individual case records (physician or provider records) that had been selected as part of random samples and outlier focused samples.

Discussion: Under the Health Care Quality Improvement Program (HCQIP), HCFA has reinvented, and is continuing to reinvent, Medicare's quality assurance programs. Over the next five years, HCQIP is expected to encompass an integrated quality management system that is emerging as part of HCFA's strategic plan.

HCQIP is based on the principle that QIPs can do more to improve the quality and cost effectiveness of care by bringing typical care into line with best practices than by inspecting to identify erred treatment in individual cases. The key HCQIP objectives are to:

- Build a community of those committed to improving quality;
- monitor and improve quality of and access to care;
- communicate with beneficiaries and providers of care so as to promote informed health choices;
- protect beneficiaries from poor care; and
- create a supporting infrastructure to make these achievements possible.

Among the primary HCQIP initiatives are:

o Local and National Improvement Projects.

As part of HCQIP local cooperative projects, QIPs work with the local health care community to identify and interpret scientifically sound parameters of practice to measure the quality of care. These parameters of care are often based on practice guidelines developed by the Agency for Health Care Policy and Research (AHCPR) as well as other authoritative clinical bodies. QIPs use statistical quality surveillance to examine variations in both the processes and outcomes of care. QIPs share these data with providers and physicians and work cooperatively with them to interpret and apply findings. HCQIP gives QIPs and HCFA a chance to demonstrate that health care provided to Medicare beneficiaries can be measurably improved.

Status: To date, QIPs have reported on 514 collaborative improvement projects. Of these, 60 have been completed, 222 are in progress and another 154 are in development. QIPs have abandoned 78 projects to date. Approximately 20 percent of projects address the use of pharmaceuticals, such as antibiotics and ACE inhibitors. Another 10 percent address the accuracy of diagnostic and procedure coding. Other projects that involve multiple PROs include blood transfusions and cardiac catheterization. In January 1995, all PROs will begin the cooperative cardiovascular project. This project will focus exclusively on the treatment of heart attacks.

- o Clinical Data Quality Surveillance.

  Under this initiative, QIPs will measure processes and outcomes of care against community-accepted clinical standards of quality and practice guidelines. Upon identifying and assessing statistical variations, QIPs will intervene and work collaboratively with hospitals and physicians to improve the delivery of care. In instances of provider incompetence and negligence, QIPs will have a stronger role in notifying licensing and certifying agencies and making sanction recommendations to the Inspector General.

  Status: Implementation is underway.

- o Investigation of Beneficiary Complaints.

  Under this initiative, revised regulations will allow for a more aggressive posture in soliciting and investigating beneficiary complaints to the QIPs and provide a more thorough and sensitive follow-up to these complaints.

  Status: Initial planning work is underway.

- o Beneficiary Education.

  HCFA will improve educational beneficiary outreach programs in health promotion and disease prevention to help beneficiaries make better health choices, and ensure that they are fully aware of their rights to quality care under Medicare.

  Status: Initial work is underway.

Budget Impact: Budget neutral. HCFA anticipates that this program change will significantly improve the quality of care provided to Medicare beneficiaries.

Use of Quality Indicators in the Medicare/Medicaid Survey and Certification Program

Issue: The current process by which HCFA can ensure provider compliance with Federal health and safety requirements involves labor-intensive, expensive, on-site "snapshot" performance surveys. Through routine site visits, over 7,000 surveyors observe, interview, and review records of 22 different Medicare and Medicaid provider and supplier categories.

Discussion: HCFA has been developing quality indicators (QIs) in nursing homes and home health agencies for use in the survey and certification process. QIs are tested, validated and reliable data-driven "markers" of outcomes of care, or processes of care, that have been shown to be predictors of outcomes of care. QI data will be collected, analyzed and shared with providers, States, HCFA, and beneficiaries.

The ability to use QI data in the survey process and provider-based internal quality improvements depends on requiring standard assessment and reporting of the critical QI data, the implementation and maintenance of a State and national data system and the development of a reliable complete data base of information reported by the facilities on individual clients.

QIs have multiple beneficial uses:

- Use by regulators in the survey process;
- use by providers in internal quality improvement;
- use by beneficiaries to inform themselves as they make critical choices for health care;
- use by professionals, researchers, social and health policy experts to inform care practices and policy; and
- use by payment policy experts to help inform payment policy.

Status: Quality indicators for nursing homes and home health agencies (HHAs) have been developed and are now being piloted in use. New HHA conditions of participation are under development, as is a new standard assessment tool for HHAs. Computerization of the existing nursing home assessment tool information is in progress. Full implementation of the nursing home project will occur in 1 to 2 years, and the home health project will be implemented in 3 to 4 years. Plans are being made to develop quality indicators for end stage renal disease facilities, hospices, and intermediate care facilities for the mentally retarded as well.

Budget Impact: The use of QI data will not replace the on-site inspection, but will enable the State survey agencies to assess provider performance throughout the year and across all the providers without actually being there all the time. This will allow diminishing survey resources for on-site inspections to be targeted to problem providers and used more efficiently.

Quality Improvement Programs Procurement Process

Issue: The procurement process in contracting with Peer Review Organizations and End Stage Renal Disease Networks (hereafter referred to as Quality Improvement Programs, or QIPs) has been time and labor intensive for both government and contractor personnel, leading to delays in completing procurement actions. On the average, it takes about 18 months to complete any major procurement action.

Discussion: HCFA has analyzed delays in the procurement process and determined ways to streamline and improve the procedure. Delays were found to occur mostly at the scope of work development stage. For example, current procedures used in developing the independent government cost estimates (IGCE) are cumbersome and difficult to use.

HCFA has determined, and will embark on, ways to streamline and improve the procurement procedure. With respect to developing IGCEs, HCFA will soon award a contract for a user friendly computer program. Other areas of improvement will include:

- Effective communication of negotiation positions among all HCFA teams prior to negotiations;
- procedures to ensure receipt of proposals by all neutral panel members for noncompetitive procurement;
- elimination of the confusion and problems resulting from having too many versions of the Requests for Contracts/Proposals;
- ways to increase administrative support during peak periods in the procurement process;
- elimination of inconsistent submission of Justification for Other Full and Open Competition.

In addition, the Social Security Act allows QIP contracts to be non-competitively renewed. HCFA has developed a streamlined procurement process for noncompetitive renewal of QIP contracts. HCFA is working with the QIPs to develop pricing principles and contract provisions based on a common understanding of the Statement of Work. HCFA intends to apply this collaborative model to other contractors and agents. Benefits derived from this approach include: reduced acquisition processing time; elimination of the need for technical proposal review for contractors who have met the renewal criteria; cost savings realized by both the QIPs and the government in the procurement process; improved understanding of contract expectations; and greater uniformity in QIPs' contract execution.

Status: Vendor proposals for the contract to develop a user-friendly program for the IGCE have been received and are under evaluation. Award of the contract will take place soon. Implementation on other areas of improvement has commenced.

Budget Impact: Cost savings have not been quantified. Full implementation of the above recommendations should reduce the processing time for PRO and ESRD procurement from 18 to 12 months.

Modifications to Requirements Under the Clinical Laboratories Improvement Amendments (CLIA)

Issue: Current CLIA requirements are burdensome, particularly for the more than 130,000 laboratories that have not been regulated previously. Burdens include: meeting comprehensive quality requirements based on the complexity of the testing performed in the laboratory, registration and other paperwork requirements, and fee payments. State survey agencies are also burdened with conducting biennial on-site surveys of approximately 40,000 laboratories to determine compliance with the complex and comprehensive CLIA requirements.

Discussion: HCFA has embarked on, or will pursue, various administrative actions to reduce unnecessary burdens.

- Categorization of Tests and Personnel Modification (HSQ-216-FC). This regulation will expand the category of microscopy tests which are exempt from inspection, and this would effectively double the number of laboratories exempt from routine survey under this provision. The rule would also give flexibility to laboratories by expanding the list of professionals who may perform moderate complexity microscopy procedures. This should reduce the burden to rural and medically underserved areas in having to compensate and recruit health personnel who are in short supply.

  Status: This rule is in the final stages of clearance prior to OMB review.

  Budget Impact: Approximately 10,000 laboratories would be exempted from routine inspections.

- CLIA Deeming Notices: HCFA has approved, as deeming certification agencies, the Commission on Office Laboratory Accreditation, the Joint Commission on Accreditation of Health Care Organizations, and the American Society for Histocompatibility and Immunogenetics. Applications from the American Osteopathic Association, the College of American Pathologists, and the American Association of Blood Banks have been received. Furthermore, the Washington State exemption from CLIA was recently re-approved for 2 years.

  Budget Impact: The deeming arrangement will reduce the number of laboratories surveyed by HCFA by 20,000 laboratories.

- Categorization and Certification Regulations for "Accurate and Precise Technology" (APT) Tests (HSQ 222-P). By creating a new subcategory of lab procedures called "accurate and precise technology" tests, this rule would reduce the burden on laboratories to comply with all of the moderate complexity testing requirements.

  Status: The Notice of Proposed Rulemaking is being prepared.

- Flexible Surveys for Small Laboratories. HCFA has devised a flexible survey which accounts for the great variability among laboratories in lab test volumes and degree of lab test complexity. Approximately 1,000 laboratories (those that are low volume or that perform only simple screening or preventive tests for ambulatory patients) will be surveyed once every four years. Laboratories will be required to respond to specific questions regarding the types of testing conducted and how they are meeting the corresponding CLIA quality requirements. Based on this information, surveyors can determine the necessity of on-site surveys.

  Status: Evaluation of the survey process is currently underway.

  Budget Impact: A flexible survey process will enhance surveyor efficiency and better utilize resources. It is expected to significantly reduce administrative costs in the first two years of the program.

- Outcome-Oriented, Performance-Based Surveys. Plans are underway to develop a more outcome-oriented, performance-based CLIA survey process.

Notes for Regulatory Review Meeting

Two issues:

1. What HHS has been doing

2. How to credit for this as a health reform initiative

Our ideas:

- HHS is working hard on this in response to pressure from us (gave them Gleason memo; requested review as part of Map Room process) and in response to the regulatory review initiative. We (Chris and Jen) are in control of both processes. The Department would probably prefer to view this as part of health care reform and get credit for what they are doing.

- We think NPR would agree that it is important for them to focus on "big ticket" regulatory changes. Because, while significant, these initiatives don't sound "bold" and "outrageous" -- the standards for the Vice President's initiative -- we can argue persuasively that these issues are better addressed as health care initiatives rather than as part of REGO II.

Examples of things HHS is doing:

- CLIA

  HHS: (1) is expanding the number of tests and therefore labs that are exempt from routine survey; (2) has approved new deemed certification agencies; (3) issued a notice of proposed rulemaking on creating a new category of lab procedures, called the "accurate and precise technology" tests, and reducing the burden on labs using these tests; and (4) decreasing survey frequency for small labs.

  In our recent discussions, HHS has gone farther to recommend the development of performance standards for CLIA and to tie survey frequency to outcomes measures.

- Simplifying communications with beneficiaries

  Stage: Development of materials; pilot project underway

- Improving and payment procedures (e.g., eliminating pre-billing attestation requirements, providing uniform identification numbers to all providers of government health services).

Stage: Underway

- Developing one "Medicare Transaction System" to replace numerous claims processing systems required by numerous insurers.

  Stage: Contract awarded

- Conditions of Participation -- replacing process requirements by performance standards.

  Stage: Notice of Proposed Rulemaking to be published in November 1995.

- Providing greater flexibility for HMOs

  Stage: Rulemaking in 1995

- Reinventing Medicare quality assurance programs

  Stage: Various programs at different stages

- Using quality indicators in Medicare/Medicaid survey and certification program

  Stage: Under development

Things on Gleason's list that are being worked on:

- Standardizing claims forms and procedures for filing claims in Federal health insurance programs.

- CLIA -- reducing compliance burdens. This is already underway. However, in recent discussions, the Department has accepted tying survey schedules to performance standards.

- OSHA's blood borne pathogens regulations are under review in the reg review process.

- Home health care -- the Department is now talking about moving to using outcomes data for home health agencies.

We wanted reg reform to ease burden on doctors, consumers

We are continuing to do that . . .

Mr. Parnage

HHS - Pull event together

CLIA

Attestation

Chris to call

Harkin -- all issues mentioned -- ought to be able to solve them

Phys. Assist, Nurse -- saying what has made a difference.

Talk to Carol & Elaine

SDON

FDA - opp. to be nice to drug cos

Am Home Products -- Immunization

HHS set purchase price too low -- cost shifting esp. OPV

→ Sara, Tim talk to Chris re others

Marcia Simon - Labor

Bill Childers - Labor

Drug approval — Stafford - Bristol

Merk

Budget document

→ Chase HSA

→ CLIA - must consult on hill

→ Consumers
  → Medicare bills

→ Reason to come
  → consumer & provider issues

Could you + Chris give me an update? Tx.

TO: Hillary Rodham Clinton
FROM: Jennifer Klein
DATE: 1/17/95
RE: Vice President's Regulatory Review Initiative

At Carol Rasco's request, I am heading the Health Industry Working Group of the Vice President's Regulatory Review Initiative (several of the working groups are headed by the DPC). We have been asked to identify new approaches to regulation that are "bold" and "customer-service oriented". Because the working groups are scheduled to make their first presentations to the Vice President in a few weeks, Carol suggested that each group focus initially on two to four areas. I wanted to give you a brief update on our group's progress.

We plan to discuss the following areas at our first presentation:

1. **Health and Safety Standards for Medicare Providers**

   Today, hospitals, home health agencies (HHA), hospices and End-Stage Renal Disease (ESRD) facilities must meet extensive procedural and administrative requirements to participate in the Medicare program. We will propose "performance" based standards to replace more traditional "process" oriented regulation. We will also recommend that flexible survey cycles (allowing discretion over the time between surveys of a facility) that currently apply only to hospitals and ESRD facilities be extended to HHAs, and that the frequency of surveys in all types of facilities be related to their ability to meet new outcomes standards.

2. **Clinical Laboratory Improvement Act (CLIA)**

   As you know, there has been a significant outcry against CLIA, particularly by physicians who claim that it places excessive and unnecessary burdens on physician operated labs that perform relatively simple tests. We will present a package of improvements, including: (1) exempting a greater number of tests (and therefore labs) from routine inspection; (2) reducing oversight of labs using advanced "black box" technology; (3) using mandatory laboratory proficiency testing to educate and inform labs about problems rather than to punish them; and (4) replacing burdensome process requirements with performance standards and flexible survey cycles.

3. **Physician Attestation**

   We have also been asked to look for what the Vice President's office calls "low-hanging fruit" -- areas that can be addressed fairly quickly and easily that will relieve regulatory burdens and reduce costs for the health care

industry. We will recommend the elimination of the requirement that physicians must sign "attestations" certifying that they have accurately reported the diagnosis and treatment for each hospital admission before submitting billing claims to the Medicare program.

We will present case studies showing the burdens imposed on real consumers and providers by these regulations, the pros and cons of the options chosen to relieve their burdens, and a discussion of the alternatives not chosen (e.g., repeal CLIA).

HEALTH INDUSTRY WORKING GROUP
SUMMARY OF OPTIONS PRESENTED

I. Physician Attestation

Problem. Currently, a physician must sign an "attestation form" (certifying the accuracy of all diagnoses and procedures) for each Medicare patient discharged from a hospital. Obtaining the physician's signature is burdensome for hospitals and physicians, and cause billing delays that hurt hospital cash flow.

New Regulatory Approach. Streamline paperwork.

Proposal. Eliminate the requirement for the form entirely and instead hold hospitals responsible for the accuracy of diagnoses and procedures. (Reg)

II. Health and Safety Standards for Medicare Providers

Problem. Hospitals, home health agencies, hospices, and end-stage renal disease facilities must meet health and safety standards to participate in the Medicare program. Currently, these regulations consist of procedural and administrative requirements rather than "outcome" measures that evaluate actual patient care.

New Regulatory Approach. Performance standards.

Proposals

- Eliminate unnecessary process requirements and instead develop outcome-based performance standards and increase consistency of requirements across providers. (Reg)
- Tailor oversight and survey frequency of home health agencies to performance.

Alternatives

- Extend use of flexible survey cycle for nursing homes.
- Completely eliminate surveys for providers with good records.

III. Clinical Laboratories Improvement Amendments (CLIA)

Problem. CLIA is unnecessarily burdensome (especially for small and physician office laboratories), and laboratories fear sanctions for failure of proficiency testing.

New Regulatory Approach. Reduce oversight for certain test systems; establish performance standards; use information and education rather than sanctions.

Proposals

- Waive the routine two year survey of users of "black box" technology. (Reg)

  Alternatives

  - Do not create new testing category.
  - Seek legislation to waive "black box" technology.

- Clarify and expand waiver criteria and streamline the waiver process. Waive all tests approved by FDA for home use. (Reg)

  Alternatives

  - Exempt all tests performed in physician office laboratories from CLIA requirements.
  - Repeal CLIA.

- Use performance standards and require less frequent on-site inspections of excellent performers. Approve private accrediting organizations for deemed status. Exempt labs from CLIA requirements when the State has requirements equal to or more stringent than CLIA. (Reg)

  Alternatives

  - Repeal quality assurance and personnel requirements (except in cytology laboratories), and rely on proficiency testing and outcomes as the bases for quality control.
  - Allow HCFA to waive these requirements for labs that perform well.

- Clarify regulations so that proficiency testing failures are used for education and as an outcome indicator in laboratory quality. Sanctions are imposed only for repeated failures or immediate jeopardy. (Reg)

  Alternative. No longer require proficiency testing.

SUMMARY OF OTHER ALTERNATIVES

I. **Competition in Medicare**. There are various proposals being discussed that are described as efforts to increase choice and competition in Medicare. The Administration is currently considering proposals (as part of health reform discussions) to offer beneficiaries greater choice among managed care plans. The Administration has opposed proposals to create a voucher system under which private insurers bid for Medicare patients.

II. **Physician Review Organizations (PROs).** Proposals have been made: (1) to set Medicare standards for hospital quality and utilization review and allow hospitals to contract for review either through PROs or other third parties; and (2) to eliminate the PRO program entirely.

III. **Ownership and Referral**. Proposals have been made to replace the current ban on self-referral (i.e., referral by physician to facilities in which they have an ownership interest) with restrictions on over-utilization.

IV. **Reimbursement Mechanisms**. Proposals have been made to change arbitrary and inefficient payment and coverage rules.

V. **Paperwork Reduction in Federal Programs**. Proposals have been made to have the Office of Personnel Management announce that their carriers accept the HCFA 1500 (which is required by Medicare and used by the Department of Defense and the Department of Veterans Affairs) and to standardize the instructions for filing the form across all of the Federal agencies that use it.

Ideas for Regulatory Relief Events

1. Simplify Billing and Payment for Providers and Consumers

- Eliminate Physician Attestation Requirement. (No action taken yet by HCFA.)

- Provide Uniform Identification Numbers to all providers in Federal health programs. (HCFA has begun work. No public statement yet.)

- Simplify the "Important Message from Medicare" -- simplify the content and way it is distributed. (Work has begun. No public statement yet.)

- Improve and simplify communications with beneficiaries -- create one, easy to understand, monthly statement. (Work has begun. No public statement yet.)

- Implement the Medicare Transaction System -- uniform, national system for processing Medicare claims to replace the 14 different claims processing systems operated by 79 insurance companies at 62 sites. (GTE was awarded design contract in January 1994; implementation will begin in 1997.)

2. Eliminate Burdensome Process Requirements for providers

- Change conditions of participation to make them more outcomes-based, less process-oriented. (These are being developed for hospitals and ESRDs. HCFA is prepared to begin developing similar standards for home health agencies. No public statement yet.)

Other possibilities:

1. CLIA -- more controversy because of conflicting provider, consumer and Hill concerns

2. Physician Review Organizations (PROs) -- HHS unwilling to go as far as many providers would like (i.e., eliminate completely). We will work with Gleason on this.

3. Fraud and Abuse activities

Health Care Presentation
Health Care Financing Administration, Bruce Vladeck
March 14, 1995

A. Physician Attestation -- Presentation of Working Group Consensus

B. Health and Safety Standards for Medicare Providers -- Discussion of Alternatives

1. Conditions of Participation: Eliminate Unnecessary Process Requirements

2. Home Health Agency Surveys: Allow Flexible Survey Cycles

C. Clinical Laboratories Improvement Amendments -- Discussion of Alternatives

1. Waive Routine Survey of Users of "Black Box" Technology

2. Clarify and Expand Waiver Criteria and Streamline the Waiver Process

   Alternatives: (1) Exempt all tests performed in physician office laboratories from CLIA requirements; (2) amend statutory "risk" language to allow consideration of benefits and costs; or (3) repeal CLIA.

3. Use Performance Standards and Require Less Frequent On-Site Inspection of Excellent Performers

   Alternatives: (1) Repeal quality control, quality assurance, and personnel requirements, and rely on proficiency testing and outcomes for quality control; or (2) give HCFA discretion to waive these requirements for labs that perform well.

4. Use Proficiency Testing Failures for Education and as Outcome Indicators for Laboratory Quality

   Alternative: No longer require proficiency testing.

D. Additional Options for Discussion

1. Paperwork Reduction in Federal Programs

2. Competition in Medicare

3. Physician Review Organizations (PROs)

4. Ownership and Referral

5. Reimbursement Mechanisms

Physician Attestation

- Total elimination of attestation form

Health and Safety Standards for Medicare Providers

Conditions of Participation

- Outcome oriented requirements
- Data for consumers and enforcement
- Consistency across the board for providers

Home Health Agency Surveys

- Fewer surveys for good performers
- Less spending and resources
- Focused on poor performers

CLIA

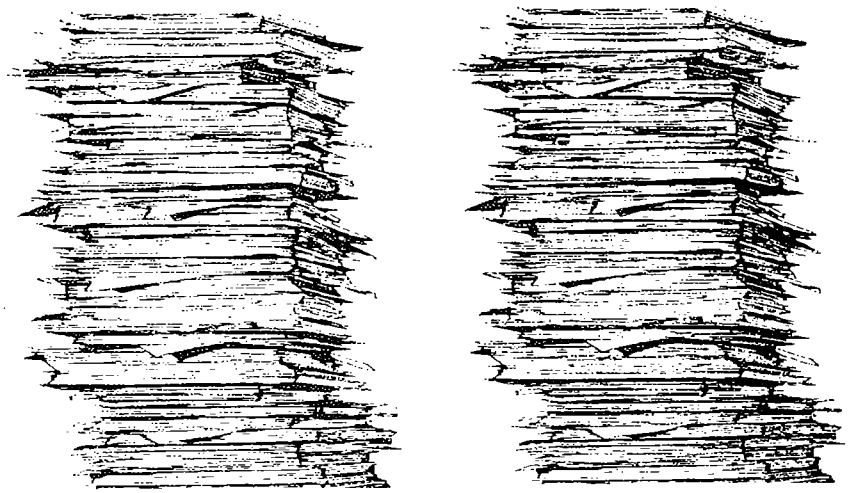
- More waived tests
- Fewer surveys for good performers
- Greatly reduce burden and lower costs for small physician office laboratories
- Educational focus for proficiency testing
- Minimal oversight for accurate and precise (Black Box) test systems

PHYSICIAN ATTESTATION

CURRENT

11 Million Attestation Forms

- 200,000 Hours Physician Time
- Hospital Billing Delays



PROPOSED

No Forms

HEALTH AND SAFETY STANDARDS FOR MEDICARE PROVIDERS

Conditions of Participation

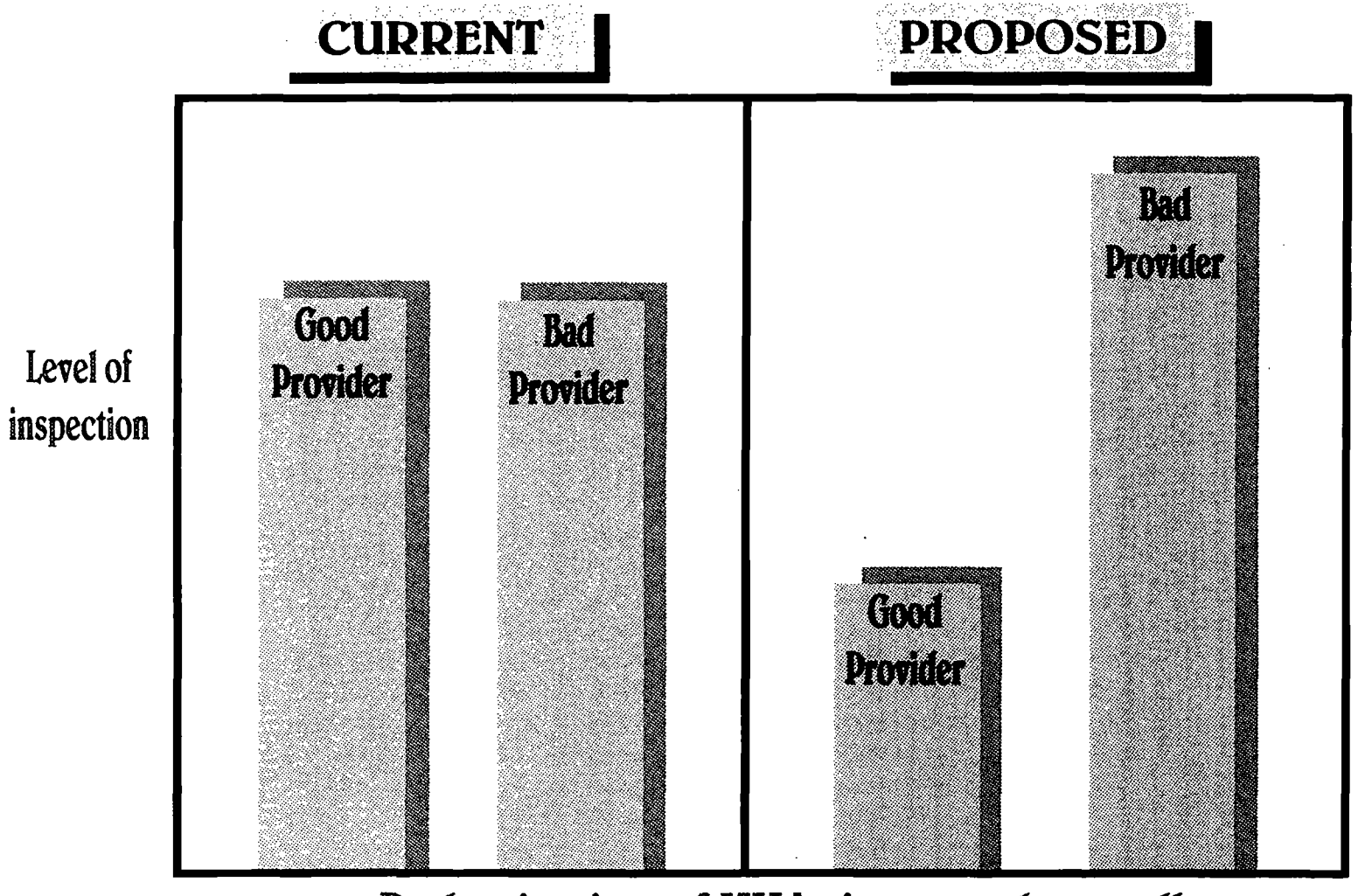
CURRENT

- Emphasis on process requirements
- No information for consumers

PROPOSED

- Emphasis on performance standards
- Information for consumers

HOME HEALTH AGENCY SURVEYS

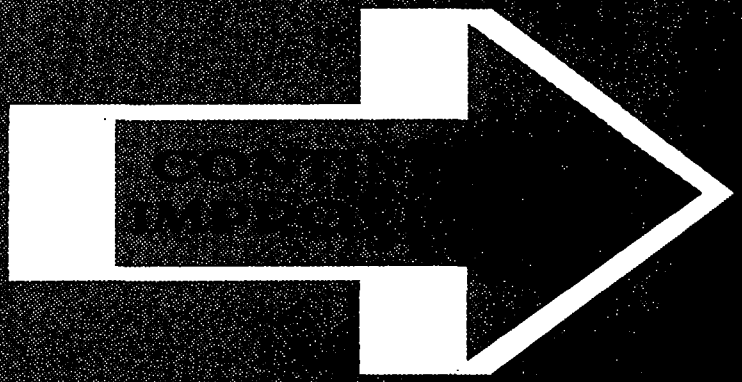


30% Reduction in # of HHAs inspected annually

$8.8 million Reduction in inspection costs

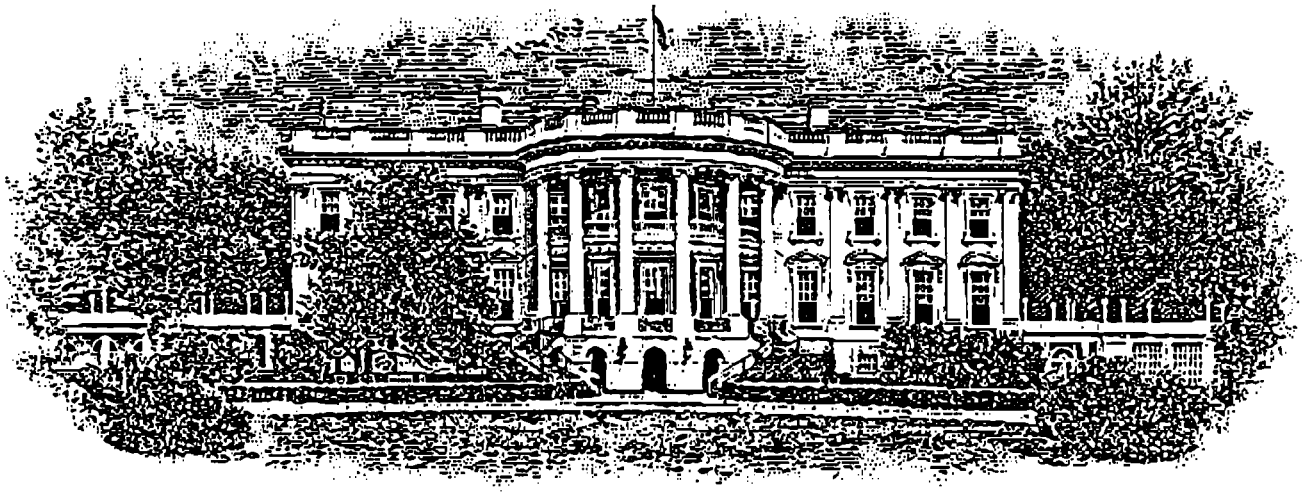
CLIA SYSTEM IMPROVEMENT

- Rigid
- Limits incentives for improved technology
- Focus on process and paperwork
- Burdensome
- Sanctions for failure
- Routine Biennial inspections



- Customer service approach
- Drives better technology
- Focus on improving outcomes
- Reduces burden
- Improvement through education
- Reduces inspection for good performers

The White House



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Jen

FAX NUMBER: 6-2878

TELEPHONE NUMBER:

FROM: Chris

TELEPHONE NUMBER:

PAGES (INCLUDING COVER): 5

COMMENTS:

FACSIMILE TRANSMISSION REQUEST

ADDRESSEE: (Name, Organization, Address)	FROM: (Name, Organization, Address)
Chris Jennings Phone: _____	Jennifer Boulanger Office of the Administrator HCFA Phone: 202-690-8502

TOTAL PAGES: (Without Cover)	ADDRESSEE'S FAX MACHINE PHONE NUMBER: (If Known)	DATE:
4 + C		1/26/95

REMARKS:

Bruce asked me to send you the write-ups of streamlining/reinventing government projects initiated during the past year that you requested.

If you have any questions, please give me a call.

Stacey –

IF FAX MACHINE RETRANSMISSION IS NECESSARY PLEASE CALL:

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to Jen –

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Cooperative Cardiovascular Project

Discussion of Problem: Quality of medical care in the Medicare program has historically been monitored by chart reviews and by the publication of diagnosis and procedure specific mortality rates for individual hospitals. These assessments are not reliable indicators of quality of care and, more important, have not led to demonstrable improvements in the quality of care for Medicare beneficiaries.

Description of Solution: Collect data on patterns of care and patterns of outcomes for selected cardiovascular conditions and work with hospitals, medical staffs, and health care groups to use these data to promote improvement in care, rather than impose prescriptive regulations on hospitals or physicians.

The Cooperative Cardiovascular Project is a national collaborative effort between the Health Care Financing Administration (HCFA), peer review organizations, physician and hospital organizations, and other groups sharing an interest in improving processes of care and outcomes of care for patients hospitalized for certain cardiovascular conditions. (The conditions are: acute myocardial infarction (AMI), coronary artery bypass grafting (CABG), and percutaneous transluminal coronary angioplasty (PTCA).) The project is based on guidelines for treatment of heart attacks prepared by the American College of Cardiology and the American Heart Association and updated with their help.

This project was piloted in hospitals in Alabama, Connecticut, Iowa, and Wisconsin and is expanding to all 50 states in 1995.

Who Benefits from this Proposal: All those involved in this project benefit. First and foremost, Medicare beneficiaries and all other patients hospitalized for the conditions that are used in this project. Hospitals and their medical staffs will find data comparing their performance with that of other institutions extremely useful, and will benefit from improved processes and outcomes.

Possible Public Event:

- A visit to a hospital located in one of the four demonstrations states (Alabama, Connecticut, Iowa, and Wisconsin) to discuss this project with physicians and patients.

Clinical Laboratory Improvement Amendments (CLIA)
Personnel Modifications

Discussion of Problem: CLIA rules link personnel requirements to the complexity of testing. The regulations list specific qualifications for the various lab positions and also define functions and responsibilities for the persons who fill these positions. These qualifications are prescriptive and require certain minimum levels of education. As a result, employees lacking formal education but possessing experience and good performance records must obtain formal education or lose their jobs.

In addition, a subcategory of moderate complexity lab tests called "physician-performed microscopy (PPM)" did not permit performance of tests by dentists or mid-level practitioners.

Description of Solution: All individuals who are engaged in laboratory testing or supervision will be able to continue to perform such testing (in the absence of evidence of poor performance). In addition, a personnel standard for laboratory testing is being established for new laboratory employees. This provides relief in those areas of the country where there are inadequate numbers of individuals who meet the academic credential requirements and the existing workforce would not otherwise be able to continue to provide laboratory services.

The definition of providers who may perform PPM tests has been broadened to include dentists, physician assistants, and nurse practitioners who routinely perform these tests, especially in medical shortage areas. This will reduce the regulatory burden for these laboratories and will enhance access to care.

Who Benefits from this Proposal: Laboratory personnel currently considered technically unqualified under current regulations will be permitted to continue performing their jobs (as long as their performance is acceptable). The stricter personnel standards would be met over time as new individuals are hired by labs.

Dentists, physician assistants and nurse practitioners will also benefit because they will be able to perform test that they were once prohibited from performing.

Possible Public Event:

- Visit a lab in an area where people have been doing this job for years, but would otherwise have lost their jobs. (List of those areas can be provided.) Would highlight both the stricter standards labs must meet as well as the governmental flexibility to recognize good performance rather than merely paper credentials.

- Visit a physician assistant or nurse practitioner in a medically underserved area. Because they will be able to perform additional tests under CLIA, access to care is enhanced.

Electronic Transactions and Information Access

Discussion of Problem: Medicare's managed care contractors were required to submit monthly plan data such as enrollment and disenrollment to HCFA by hard copy or computer tape. Information would be updated by HCFA and resubmitted to the managed care plans. Managed care plans desiring statistical data, such as payment rates or demographic information, would write to HCFA which would in turn, mail a document with the requested statistics. This process was costly and time-consuming.

Description of Solution: HCFA now allows and encourages all Medicare managed care contractors to submit monthly plan data electronically, directly to the HCFA Central Office. In addition, managed care contractors have on-line access to beneficiary data and reimbursement rates, and HCFA has established a system of electronic notification of invalid reimbursement and enrollment transactions and other reports.

Who Benefits from this Proposal: Managed care plans that contract with Medicare now have immediate access to relevant program information and can submit required information in a less burdensome manner. In addition, the Federal Government (HCFA) benefits from a reduction in processing time and effort, and the improved accuracy of the electronically submitted data.

Possible Public Event: A managed care plan such as Kaiser could demonstrate their new access to program information and the ease with which the plan information is submitted to HCFA.

Eliminate Physician Attestation Requirement

Discussion of Problem: A physician must sign an "attestation form" for each Medicare patient discharged from an acute care, inpatient hospital. The form is used to certify the accuracy of all diagnoses and procedures for each patient and must be signed by the physician before the hospital can submit a bill for Medicare payment. Obtaining the physician's signature has proved a cumbersome burden for hospital and physicians, and the delays hurt hospital cash flow.

Description of Proposed Solution: Eliminate the requirement for the form entirely. Hold hospitals responsible for the accuracy of the medical abstract. Improvements in hospital record keeping and coding capabilities make hospitals the appropriate focus for combatting any fraud and abuse.

Who Benefits from this Proposal: Both hospitals and physicians will benefit. Savings to hospitals will result due to reduced labor costs and the ability to bill Medicare more promptly. Physicians will no longer by "hassled" by this requirement.

Possible Public Event:

- A press conference in a large hospital's medical records room. Hospital's must now "chase down" physicians in order to obtain the needed signature for every Medicare beneficiary admission. The medical records as a backdrop would display how burdensome this requirement has been.

- A press event where a hospital retraces the steps it would go through to obtain the physician's signature. (Some hospitals have hired people to take taxis to go to physician offices to obtain the signatures.)

"Incorporate the suggestions I've highlighted. Indicate why we have not recommended these alternatives.

More ideas for CLIA reform that look beyond bed side and physician office technologies. . .

General thoughts

Deemphasis of proficiency testing has its drawbacks since it is the principal performance measure for laboratory testing. As I recall, the statute mandates that laboratories disseminate proficiency testing measures. At a minimum, this dissemination should continue, even if HCFA does not impose traditional sanctions. The following reforms are premised on the assumptions that proficiency testing will be improved as a science and labs will disseminate performance information to the public:

1. Flexible Survey Cycle for Moderate and High Complexity Labs: As with other enforcement programs, HCFA should consider varying the two year cycle based on historical survey performance (and perhaps proficiency testing performance.) Superior laboratories that maintain the same test menus, ownership, and significant laboratory personnel (e.g. laboratory director, general supervisor, etc.) should be able to certify after two years that nothing has changed and thereby would be exempt from another survey. This exemption also could be contingent on regular dissemination of proficiency testing results to the public. Labs with minor changes to test menus (i.e. no tests falling into a higher category) could qualify for an "abbreviated" survey after two years. These changes would require statutory amendment. Hospital based labs may benefit from this policy option . This option is more expansive than the APT (black box) proposal offered by HCFA.

2. Eliminate Work Load Limitations for Cytotechnologists: This statutory provision is an excellent example of HCFA's tendency to rely on process rather than performance based regulation. HCFA should have enough experience by now to revisit work load limits for cytotechs. We should ask them whether this has been an effective policy (in reducing moonlighting, improving test accuracy) or whether it has been an administrative nightmare. Also, although HCFA has interpreted the statutory requirements as covering only manual, qualitative testing, the literal statutory language fails to consider new cost effective technologies for reading and categorizing pap smears. Again, dissemination of survey and proficiency testing data should be adequate. This change would require statutory amendment. Independent laboratories may benefit from this policy option.

3. Amend Statutory "Risk" Language to Allow Consideration of Net Benefits and Costs: Although HCFA has been more reasonable in interpreting the phrase "no risk of an erroneous test result," over time this language could be problematic. Last Administration, HCFA argued that it could not waive home test kits from CLIA regulation, because there existed some risk of an erroneous result for a given patient with such tests. Now HCFA and CDC have agreed to waive home test kits, but the statutory language possibly could justify costly regulation in the future. HCFA should amend the waiver provision to allow for consideration of net costs and benefits for all patients.

4. Update on Effectiveness of the Emergency Testing Waivers: HCFA should evaluate whether its current emergency waiver policy has been effective in ensuring access to testing in situations when the risks to a patient for not having timely test results exceed the risks of an erroneous test result. As I recall, HCFA allows labs to perform tests without CLIA approval if they report such testing within 30 days or so. I cannot remember if they allow testing in a higher complexity category or not. It would be interesting to know how frequently labs have used these waivers and under what circumstances. Revisions that ensure patient access to emergency testing may be justified.

5. Deletion of Costly Personnel Credentialling for Moderate and High Complexity Labs: Under CLIA '88, HCFA has broad discretion in establishing personnel standards for laboratory personnel. However, particularly for high complexity labs, the existing regulations continue to apply complex standards to all levels of personnel, down to the technician level. Since the 1960s, these standards have been extremely onerous for the independent laboratory industry. Now CLIA '88 applies these prescriptive standards to hospital based labs as well. HCFA should consider regulating independent and hospital based labs (mostly moderate and high complexity labs) as hospital based labs were treated before implementing CLIA '88, which is to establish qualifications only for the laboratory director and to provide labs full flexibility to hire qualified individuals that will perform accurate testing. Since publication of the initial CLIA regulations, HCFA has been "back paddling" by grandfathering many of its personnel standards. This should be viewed as an indication that such detailed regulation is not appropriate for the Federal government, and discretion in this area should be left to laboratories. HCFA should have difficulty defending continued regulation in this area, if it continues to enforce work load limitations on cytotechnologists or participation in proficiency testing. The great appeal of this regulatory reform is that it would not require statutory amendment.

Finally, HCFA should provide a summary of the laboratory deficiencies that it has identified since implementing CLIA. HCFA's regulatory proposals should be consistent with the incidence of such deficiencies and the patient risks imposed by them. HCFA must be able to use survey data to defend its decision not to repeal CLIA entirely, or even particular provisions of CLIA.

HEALTH INDUSTRY WORKING GROUP RECOMMENDATIONS

I. PHYSICIAN ATTESTATION

PROBLEM: Currently, a physician must sign an "attestation form" for each Medicare patient discharged from a hospital. The form is used to certify the accuracy of all diagnoses and procedures; without an attestation form, the hospital cannot bill Medicare. Obtaining the physician's signature is burdensome for hospitals and physicians, and resulting billing delays hurt hospital cash flow.

REGULATORY APPROACH: Streamline paperwork.

PROPOSED SOLUTION: Eliminate the requirement for the form entirely and instead hold hospitals responsible for accuracy of the diagnoses and procedures. Hospitals are better equipped to combat fraud and abuse given improvements in record keeping and coding capabilities. (This change can be implemented by regulation.)

PROS:

- Reduces paperwork burden and "hassle" on physicians and hospitals.
- Can be implemented quickly, with an immediate impact on providers.
- Implements recommendation by the Medicare Technical Advisory Group which is comprised of hospitals, intermediaries and trade associations.
- Decreases administrative costs for hospitals.
- The attestation requirement appears unnecessary. There has never been a prosecution in the 11 years of operation of the prospective payment system for hospitals.

CONS:

- Although the hospital will be responsible for accuracy of the diagnoses and procedures, this may create the impression that the Health Care Financing Administration (HCFA) is relaxing its controls on fraud.
- Despite coding/DRG complexities, physicians are viewed as most knowledgeable on care given to hospitalized patients. This may create the impression that administrators rather than doctors control patient care.

Revised 2/16/95

REGULATORY IMPACT:

- 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.

II. HEALTH AND SAFETY STANDARDS FOR MEDICARE PROVIDERS

PROBLEM:

- Hospitals, Home Health Agencies (HHAs), hospices, and End-Stage Renal Disease (ESRD) facilities must meet health and safety requirements to participate in the Medicare program. These requirements measure "process" (i.e., procedural and administrative requirements as proxies for quality health care) rather than "outcome" (i.e., evaluations of actual patient care) and continuous quality improvement.

- 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.

- Very little information is available for consumers on the quality of care at a given facility. Information about quality can help consumers make health care choices.

- 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.

REGULATORY APPROACH: Performance standards; tailor oversight and survey frequency to performance.

PROPOSED SOLUTIONS:

A. 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.

(These changes can be implemented by regulation.)

PROS:

- 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.

CONS:

- Eliminating unnecessary process requirements may be viewed by patient advocates as an elimination of patient safeguards.
- Developing patient care data requirements could be viewed as an additional burden for some providers because they do not currently report this data to HCFA.

REGULATORY IMPACT:

- Produces savings because providers are free to achieve high quality outcomes in the most cost-effective manner. (Note: Outcome measures focus on results whereas process regulations require providers to follow certain procedures. To the extent we can evaluate quality by looking at results, we can discontinue the use of required procedures).

B. Seek an amendment to Section 1891(c)(2)(A) of the Social Security Act to allow flexible survey schedule for HHAs.

PROS:

- Reduces burden on good providers (on-site inspections involve extensive provider staff participation).
- Enables survey agencies to target scarce on-site survey resources to problem providers.
- Reviews problem providers more thoroughly, which will improve care or get them out of the program.
- Provides a positive incentive to furnish good care continuously.

CONS:

- Some out-of-compliance HHAs may fall through the cracks under a flexible system.

REGULATORY IMPACT: Approximately $8.8 million in savings to the Federal Government.

ALTERNATIVES NOT RECOMMENDED:

(1) Seek flexible survey cycle for nursing homes.

(2) Eliminate surveys altogether for providers with good records.

WHY NOT RECOMMENDED:

(1) Current nursing home survey cycle allows some discretion (i.e., allows a maximum of 15 months between surveys for a given home while requiring a 12 month average for each State). Greater flexibility would be inappropriate due to the vulnerability of the nursing home population, generally low level of professional supervision, and historical problems with the quality of nursing home care.

(2) Quality of care at an institution can go from good to bad virtually overnight as a result of change of ownership, high turnover of non-professional staff, loss of key professional staff, reduction in census/client base, changes in patient mix (e.g., influx of patients who need hi-tech care), etc. Flexibility in surveying all providers reduces costs while keeping all providers alert to the possibility of inspection.

III. CLIA

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 in the laboratory, rather than where the test is performed. Compliance with the standards is determined through on-site inspection.

PROBLEM: CLIA is unnecessarily burdensome (especially for small and physician office laboratories), and laboratories fear sanctions for failure of proficiency testing.

REGULATORY APPROACH:

- Reduce oversight for certain test systems.
- Establish performance standards.
- Use information and education as a substitute for sanctions.

PROPOSED SOLUTIONS:

A. Waive the routine 2-year survey of users of "black box" technology, conducting surveys only if there are indications of problems or complaints, and to validate a 5% sample. 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. Black box technology refers to simple and easy to use test systems that have demonstrated accuracy and precision through scientific studies. (These changes can be implemented by regulation.)

PROS:

- 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.

CONS:

- Less oversight and monitoring of quality in physician office laboratories.

REGULATORY IMPACT: The dollar magnitude of savings cannot be predicted.

ALTERNATIVES NOT RECOMMENDED:

(1) Do not create new testing category to recognize "black box" technology.

(2) Seek legislation to waive all requirements for "black box" technology.

WHY NOT RECOMMENDED:

(1) Limits incentives to develop new technology and does nothing to reduce burden.

(2) Our approach achieves a similar end administratively without requiring a statutory change.

B. Clarify and expand the waiver criteria and streamline the waiver process so that more tests can be waived from CLIA requirements. In addition, waive all tests approved by FDA for home use; i.e., tests that do not require trained personnel. (These changes can be implemented by regulation.)

PROS:

- 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.

CONS:

- Removes quality protections for a greater number of tests.

- Major groups of laboratory professional scientists such as the American Society of Clinical Laboratory Scientists and the College of American Pathology may protest this reduction in requirements.

REGULATORY IMPACT:

- Eliminates inspection fees for many of the 60,000 physician office and other small laboratories that 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.

- Minimizes regulatory requirements.

ALTERNATIVES NOT RECOMMENDED:

(1) Exempt all tests performed in physician office laboratories from CLIA requirements.

(2) Amend statutory "risk" language to allow consideration of net benefits and costs.

(3) Repeal CLIA.

WHY NOT RECOMMENDED:

(1) Complex tests, if incorrectly performed, can cause irreparable harm to a patient. Data from inspections indicate that a significant percentage of tests critical to the diagnosis and treatment of patients are not accurately performed.

(2) A proposed waiver rule has already been developed that delineates a set of criteria to objectively define what constitutes a test that will have negligible risk of an erroneous result, thus allowing for waiver from CLIA standards. Once these criteria are finalized and disseminated, manufacturers and others will have a clear understanding of negligible risk. Manufacturers will have incentive to produce high quality tests that are accurate and precise and have only a negligible risk of error.

(3) Due to serious problems (e.g., incorrectly read Pap smears), public concern has demanded oversight of laboratory testing in the U.S. HCFA inspections have since confirmed the existence of quality problems.

C. 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 labs from CLIA requirements when the State where they are located has requirements equal to or more stringent than CLIA's. (These changes can be implemented by regulation.)

PROS:

- Reduces inspection burdens.
- Rewards good performers with fewer inspections. This is a positive incentive to improve performance.
- Educational emphasis on the inspection process has generated a positive response from the laboratory community.
- Approving organizations for deemed status offers laboratories oversight by peers.
- Approving States for CLIA exemption allows expanded role for States with strong licensure programs.

CONS:

- Without frequent inspections of all laboratories quality may decline.

REGULATORY IMPACT:

- Less oversight.
- Lower burden for laboratories.
- Lower user fees needed to offset the costs of the inspections.
- Deemed status allows for privatization; State exempt status allows for State role.

ALTERNATIVES NOT RECOMMENDED:

(1) Repeal quality control, quality assurance, personnel requirements (except in cytology laboratories), while relying on proficiency testing and outcomes as the basis for quality control.

(2) Amend the statute to allow for waiver of quality control, quality assurance and personnel qualification requirements to allow HCFA to waive such requirements for high performing laboratories.

WHY NOT RECOMMENDED:

(1) Elimination of quality and personnel requirements will have an adverse impact on the accuracy of laboratory tests and their use for patient diagnosis and treatment. It is important to note that:

- Inspection data indicate that significant numbers of laboratory tests are not accurately performed; good quality control and quality assurance practices are not being followed by many laboratories.

- Proficiency testing results reveal that the failure rates for previously unregulated labs are double that of previously regulated labs.

- Deficiency rates in physician office laboratories are two to three times that of previously regulated labs.

(2) Adherence to quality and personnel requirements is what defines sound laboratory practices in high performing laboratories. If these requirements are waived there would be no standards available to evaluate the laboratory in the event their performance deteriorated. Further, proficiency testing alone is unreliable as the sole indicator of laboratory performance.

D. 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 (i.e., 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. (This change can be implemented by regulation.)

PROS:

- Less intrusive than traditional regulation and oversight.

- Reduces anxiety in the physician office laboratory community while maintaining opportunity for self-assessment and improving performance.

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

CONS:

- Difficult to prevent egregious disregard for quality testing.
- Physicians do not think that this action by itself reduces burden sufficiently.

REGULATORY IMPACT: Minimizes the fear of sanctions in 60,000 non-waived labs.

ALTERNATIVES NOT RECOMMENDED: No longer require proficiency testing.

WHY NOT RECOMMENDED: Proficiency testing is a valuable outcome indicator and educational tool.

Physician Attestation

- Total elimination of attestation form

Health and Safety Standards for Medicare Providers

Conditions of Participation

- Outcome oriented requirements
- Data for consumers and enforcement
- Consistency across the board for providers

Home Health Agency Surveys

- Fewer surveys for good performers
- Less spending and resources
- Focused on poor performers

CLIA

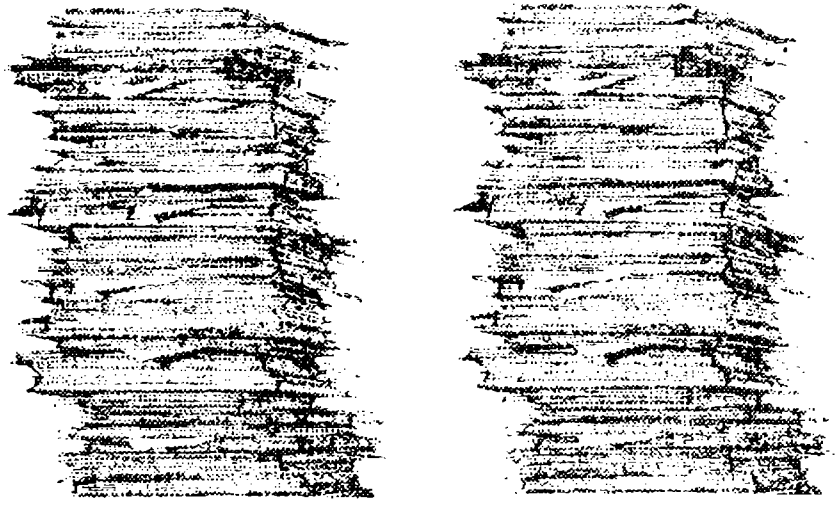
- More waived tests
- Fewer surveys for good performers
- Greatly reduce burden and lower costs for small physician office laboratories
- Educational focus for proficiency testing
- Minimal oversight for accurate and precise (Black Box) test systems

PHYSICIAN ATTESTATION

CURRENT

11 Million Attestation Forms

- 200,000 Hours Physician Time
- Hospital Billing Delays



PROPOSED

No Forms

HEALTH AND SAFETY STANDARDS FOR MEDICARE PROVIDERS

Conditions of Participation

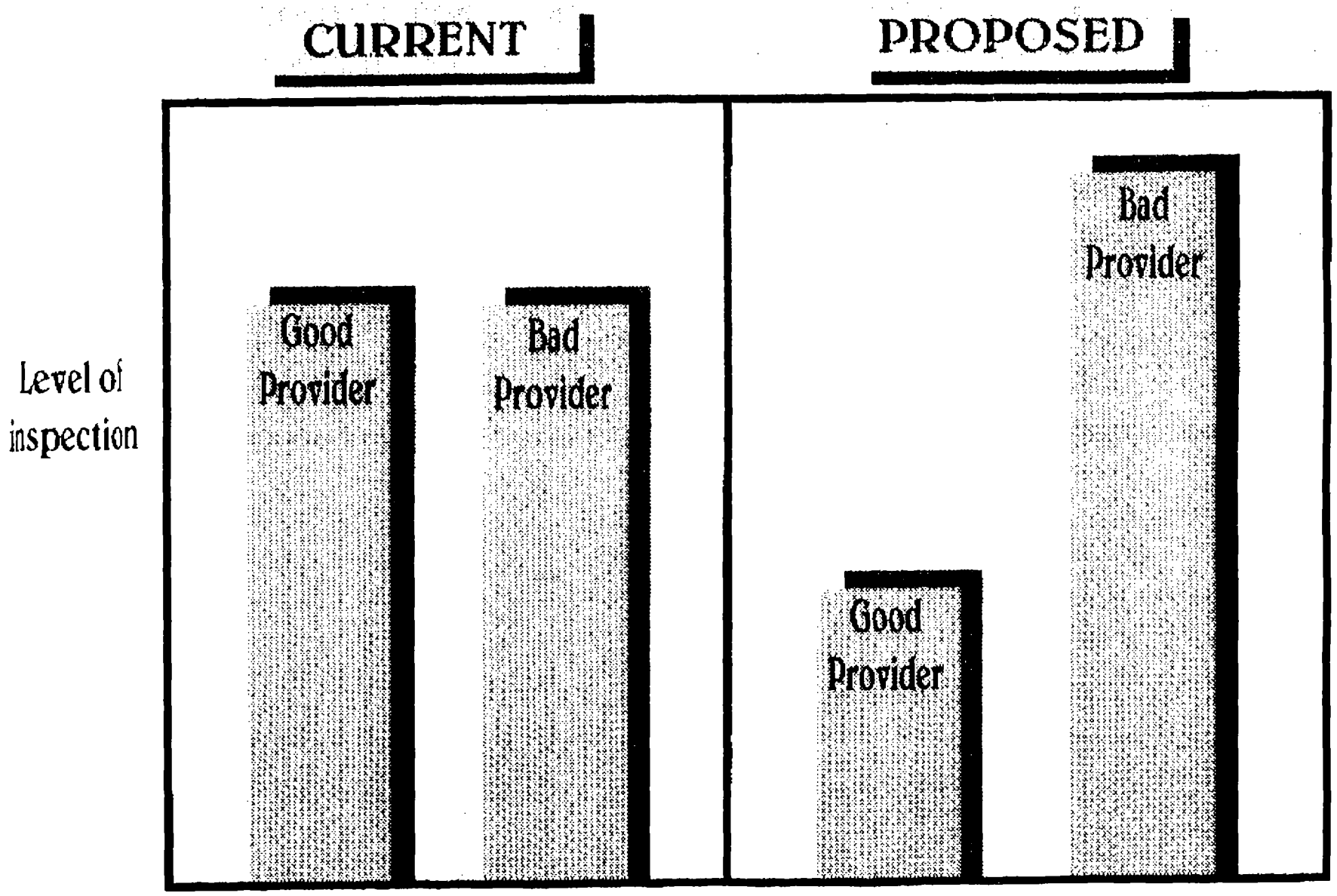
CURRENT

- Emphasis onprocess requirements
- No information for consumers

PROPOSED

- Emphasis on performance standards
- Information for consumers

HOME HEALTH AGENCY SURVEYS



30% Reduction in # of HHAs inspected annually

$8.8 million Reduction in inspection costs

CLIA SYSTEM IMPROVEMENT MODEL

Current

- Rigid
- Limits incentives for improved technology
- Focus on process and paperwork
- Burdensome
- Sanctions for failure
- Requires Biennial inspections

Inspection Experience • Data

CONTINUOUS IMPROVEMENT

Customer Feedback

Proposed

- Customer service approach
- Drives better technology
- Focus on improving outcomes
- Reduces burden
- Improvement through education
- Reduces inspection for good performers

EXECUTIVE OFFICE OF THE PRESIDENT
COUNCIL OF ECONOMIC ADVISERS
WASHINGTON, D.C. 20500

January 5, 1995

Post-it™ brand fax transmittal memo 7671 | # of pages ▸ 1

To Jennifer Klein	From Jon Baker
Co.	Co. CEA
Dept.	Phone # 55614
Fax # 6-2878	Fax #

MEMORANDUM FOR JENNIFER KLEIN, NEC

FROM: JON BAKER JBB
ERIC WOLFF

SUBJECT: Regulatory Reform Ideas in the Health Care and Food and Drug Sectors

Jon to do
1 D?

In response to your request for "brainstorming" ideas, here are some regulatory reform possibilities in the health care sector that the working group should consider.

1. Encourage health insurers to adopt a single, universal insurance claim form by requiring that FEHBP insurers collectively develop and accept such a form.

2. Make it easier for states to obtain Medicaid waivers from HCFA.

Bold ✓

3. Reinvent Medicare as a voucher plan, allowing private insurers to bid for Medicare patients and giving the insured choice among health plans. (More narrowly: apply only to people retiring after, say, 2002.)

4. Reinvent veterans care as a voucher plan, under which the VA hospital system would bid against other hospital care providers for veterans. (Possible alternative: refocus the VA hospital system on mental health care, providing other medical care through a voucher system.)

5. Give states ERISA waivers to permit them to regulate firms with single-state self-insured plans. (More broadly: integrate Federal (ERISA) and state regulation of health insurance.)

Federalism

6. Block grant to the states the funding of all or part (e.g., care for the disabled, and long term care for the aged) of the Medicaid program (developing standards for the states to ensure accountability).

7. Review the necessity of performing functions of the Public Health Service (e.g., the Bureau of Health Manpower) and look for ways to combine other PHS functions with Medicaid.

We understand that agricultural inspection reform will be addressed by the agricultural working group rather than the food and drug working group; if we are incorrect, we may have some additional ideas to forward.

TO: Claudia Cooley
FROM: Jennifer Klein jk
DATE: 1/20/95
RE: Reg Review

I just wanted to clarify what I think you are all doing.

1. Editing chart. I sent a model yesterday.

2. Preparing case studies (to bring some reality to this exercise).

3. Commenting on and adding to Shannah's "B list" when we get it.

4. Creating a list (building on the memos you already have, e.g. December 93 and 94) of regulatory review initiatives currently underway at HHS.

Let me know if you have a different understanding. Thanks again for all of your efforts.

Reinvent Medicare as a voucher plan for people retiring after 2002, allowing private insurers to bid for Medicare patients and giving the insured choice among health plans

PRO

a. Creates competition among insurers for the business of Medicare patients, encouraging insurers to reduce their own operating costs, provide attractive benefit packages to Medicare patients, and find ways of buying medical care for lower costs

b. Gives the insured choice among health plans

c. Could help contain Medicare costs over the long run, if managed care providers bid aggressively for Medicare customers

CON

a. If the reinvented program is perceived as cutting benefits to those now or soon to be Medicare recipients, it will generate political opposition; this concern may be mitigated by limiting application to those retiring after a future date

b. Unless the terms of the Medicare insurance policy are specified, insurers are forbidden from refusing to renew a policy, and price increases for policy renewals are capped, adverse selection (cream-skimming) by insurers may lead to gaps in the practical availability of coverage and to unnecessarily high costs of providing insurance

c. If insurers are free to vary policy terms, some plans will not cover some conditions presently covered

d. Some plans (e.g. HMOs) will limit insured choice of doctor or hospital

Encourage health insurers to adopt a single, universal insurance claim form by requiring that FEHBP insurers collectively develop and accept such a form

PRO

a. A universal claim form would reduce the paperwork burden for health care providers and insured patients

b. Such a form could serve as an industry standard

c. Requiring FEHBP insurers to develop the form collectively encourages industry buy-in

CON

a. If some insurers need information that most other insurers do not need, the form will be unnecessarily complex

b. Nothing guarantees that insurers will use the form for non-FEHBP claims, even if they are FEHBP insurers

Proposed Solution:

Problem:

2. ~~Streamline Paperwork~~: Many small businesses, local governments, and citizens know their Federal government primarily through its forms and reporting requirements. Because these are frequently unintelligible, duplicative, burdensome, or annoying, they are among the most often criticized aspects of the government. In fact, to many, paperwork is the Federal government.

Regulatory Approach:

Streamlining government paperwork can be done through a number of means:

(1) Establishing a "paperwork budget" and reducing "burden hours" by a specific percentage (the theory underlying the Paperwork Reduction Act);

(2) Giving agency heads authority to waive information requirements if it can be demonstrated that certain information can be more effectively collected by another means or from another source;

(3) Precluding incorporation of the actual form in rules so it can be modified without full notice and comment procedures.

(4) Using technology to make information easier to submit and to make better use of information submitted.

Pros

- -- Addresses a major public complaint about government.
- -- Reduces costs and burdens, particularly on small businesses.
- -- Facilitates changes based on experience, changed circumstances, etc.

Cons

- -- Percentage reduction is arbitrary.
- -- Information is needed for compliance and enforcement.
- -- If form is not in rule, question may arise about enforceability.
- -- Not all regulated entities are computerized.

Current Uses: The Paperwork Reduction Act gives some authority to OIRA for (1) and (4), but there has been no higher level reinforcement. Some agencies routinely follow (3).

Potential Uses: All agencies could take paperwork burden more seriously.

Alternatives Not Selected:

Regulatory Impact:

"C" LIST
1/27/95

ADMINISTRATIVE AND REGULATORY REVIEW INITIATIVES

Since the beginning of President Clinton's Administration the HCFA has undertaken various actions to reduce unnecessary burdens on the health care provider community and consumers? A list of HCFA adminstrative and regulatory review initiatives follows. (Note that information on three conditions of participation proposed rules, which will be included in the Department's presentation to the Vice President, are also included at the end of this list).

Medicare Transaction System.

At present, Medicare and its providers must cope with 11 different claims processing systems operated by 79 insurance companies at 62 sites. Information flow from Medicare to providers, and vice versa, is unnecessarily slow, complex, and costly. HCFA has awarded a contract for the development, testing and implementation of a new Medicare Transaction System (MTS). This uniform, national system for processing Medicare claims will replace the diverse existing systems and significantly simplify administrative operations for beneficiaries, providers, and Medicare. By enhancing HCFA's ability to detect and prevent fraud, MTS will protect the integrity of the Medicare Trust Funds. HCFA awarded the design contract for the MTS in January 1994. Implementation will begin in 1997. This initiative will impact all providers of Medicare Services and Medicare beneficiaries. It will improve service to providers by using standardized claims submission requirements which include formats and protocols coordinated with the industry. Additionally, it will promote a single point of contact to provide quick and easy access to beneficiary information, eligibility and claims status.

Billing and Payment Improvements

Providers have grown increasingly frustrated with the administrative burden and complexity of Medicare's billing procedures. HCFA is undertaking several actions to streamline billing and payment procedures. In addition to eliminating the Pre-Billing Attestation requirement, HCFA is leading an effort involving other Federal payers of health services, including the Department of Veterans' Affairs, the Department of Defense, and State Medicaid agencies to provide unique provider identification numbers to all providers of government health services. Having uniform provider numbers for all government health programs will make it easier for physicians and suppliers to complete billing forms across Federal programs. HCFA expects to begin assigning

new provider numbers by the end of 1996, before implementation of MTS. This initiative will impact 1.3 million providers of Federal health services.

Coordination of Benefits

HCFA has developed standard formats for carriers and intermediaries to send processed claims information to other insurers. Use of these standard formats allows insurers to enter into trading partner agreements with the maximum number of Medicare contractors. When insurers have trading partner agreements with Medicare contractors, beneficiary claims are filed automatically. This will enhance and improve providers ability to submit claims to more than one payer. Ideally these systems will determine when Medicare would be the Secondary payer.

Transforming Medicare Peer Review.

Until recently, HCFA through its contractors -- Peer Review Organizations and ESRD Networks, hereafter referred to as Quality Improvement Programs (QIPs) -- monitored quality mainly through a detection program. This was accomplished primarily through the intensive review of individual case records (physician or provider records) that had been selected as part of random samples and outlier focused samples. HCFA is reinventing Medicare's quality assurance programs. The Health Care Quality Improvement Program (HCQIP) is based on the principle that QIPs can do more to improve the quality and cost effectiveness of care by bringing typical care into line with best practices than by inspecting to identify erred treatment in individual cases. It is a non-punitive approach in which QIPs measure processes and outcomes of care against community-accepted clinical standards of quality and practice guidelines. Upon identifying and assessing statistical variations, QIPs will intervene and work collaboratively with hospitals and physicians to improve the delivery of care. Implementation of HCQIP is underway. HCFA anticipates that it will significantly improve the quality of care provided to Medicare beneficiaries.

PRO Review of Hospitals

Peer Review Organization efforts to help improve the quality of care provided in the acute care hospital setting since 1984 has been based, in the main, on information gathered from the review of significant percentages of hospital medical records. While the percentage at the outset of the program approximated 50 percent of discharges, HCFA has steadily lowered the number so that in the present contract cycle it is more nearly 8%. Through

the provisions of the current PRO Scope of Work, the number of individual cases reviewed will decrease to 1% by the end of this calendar year. This will result in the immediate benefit of decreasing the number of medical records required to be photocopied by the hospitals and transmitted to the PROs as well as significantly reducing the paperwork burden affecting hospitals and their staffs in reacting to individual case queries raised by the PROs. For the current year, this represents a reduction of approximately 700,000 hospital records.

PRO Quality Review of HMOs

The Peer Review Organizations currently review the quality of care provided to Medicare enrollees by risk-based managed care plans primarily through the review of a random sample of approximately 50,000 medical records reflecting care provided over a 12 month period of time. This presents an administrative burden to the plans in terms of identifying enrollees who have used services, ascertaining where the enrollee received services during the 12 month period and obtaining the medical records for that period. HCFA is now in the process of redirecting PRO activity to focus on quality improvement collaborations with the plans beginning with the development of valid and accepted quality indicators. Clearly the administrative burden on plans will be lessened and we anticipate the PROs having more impact on helping plans identify and improve areas showing quality deficits.

Use of Quality Indicators in the Medicare/Medicaid Survey and Certification Program

The current process by which HCFA can ensure provider compliance with Federal health and safety requirements involves labor-intensive, expensive, on-site "snapshot" performance surveys. Through routine site visits, over 7,000 surveyors observe, interview, and review records of 22 different Medicare and Medicaid provider and supplier categories. HCFA is developing quality indicators (QIs) in nursing homes and home health agencies for use in the survey and certification process. QIs have been shown to valid and reliable predictors of outcomes of care. The collection of QI data, while not representing a wholesale replacement of on-site surveys, will give HCFA a better measure of quality and allow the agency to target survey resources on providers with a history of poor performance. QIs for nursing homes and home health agencies and are now being piloted. Plans are underway to develop QIs for end stage renal disease facilities, hospices, and intermediate care facilities for the mentally retarded.

Coordinated Quality Review

HCFA is working with other public and private entities to reduce the administrative burden on managed care plans, and to identify ways to improve efficiencies in the quality review process. Initiatives are underway to establish methods for joint federal and state review of managed care plans, and to encourage state Medicaid, insurance and health care agencies to coordinate their oversight of managed care plans. These activities will reduce fragmentation among governmental entities, and decrease the activities currently required for managed care plan compliance with competing authorities.

Electronic Transactions and Information Access

The HCFA Regional Offices have significantly reduced the administrative burden on Medicare managed care contractors by allowing them to submit monthly enrollment and disenrollment data electronically, rather than with tapes or hard copies. We have also given our contractors on line access to beneficiary data and AAPCC rates, and electronic notification of invalid reimbursement transactions.

Medicaid Freedom of Choice (§1115) Demonstrations

The Medicaid Managed Care Division established two streamlined waiver applications for capitated and primary care case management program requests. The improved applications have reduced the administrative burden on states, and improved HCFA's waiver application processing rate.

Requirements for Annual Physician Acknowledgement of Physician Attestation Responsibilities

On March 9, 1994, we published a final rule with comment period that revised the regulations that required a hospital to obtain, on an annual basis, from each attending physician, a signed acknowledgement that the physician understands the penalty for misrepresenting the information on an attestation statement relating to principal and secondary diagnoses and major procedures performed on patients. The revised rule eliminated the requirement for an annual acknowledgement statement. Instead, the new rule requires a physician to sign an acknowledgement statement only upon being granted admitting privileges at a hospital. This change reduced an unnecessary paperwork requirement for hospitals and physicians associated with the processing of claims under Medicare. The next step will be to the reduce burdensome requirement that physicians must sign an

attestation certifying the accuracy of diagnoses/procedures for all hospital admissions under the prospective payment system. This new initiative is included as one of the Department's major proposals to the Vice President.

Medicare; Part B Advance Payments to Suppliers Providing Services Under Medicare Part B

Currently, there are no regulations or guidelines under Medicare Part B for making advance payments. In some instances a large backlog of pending claims may occur. Consequently, we plan to authorize (under certain circumstances) "advance payments" for the pending, backlogged claims in order to mitigate cash flow problems that may occur for suppliers and to avoid payment of interest on claims that are not processed timely. We published a proposed rule on July 18, 1994. Under this proposed regulation providers may receive partial payment whenever the carrier is not able to process claims. These advance payments are subject to later payment adjustment or recoupment once the underlying claims are processed in the normal manner. This procedure will provide relief to providers during situations that are beyond their control.

Flexible Medicare and Medicaid Survey Cycles

Medicare and Medicaid inspections of health care facilities for all providers except home health agencies and nursing homes are done using a flexible survey cycle. On average, at the FY 1996 budget request level, hospitals, ESRD facilities, hospices and other providers are surveyed every five years. The frequency of a survey for any provider is a function of their past, and suspected current performance: providers with poor compliance histories and/or current consumer complaints are surveyed more frequently than providers with good performance records.

Burden Reduction in the CLIA Progran

A CLIA regulation was published that extended effective dates for individuals enrolling in cytology proficiency testing (16,000 individuals read Pap smears); extended the phase in of quality control standards for unmodified, moderate complexity tests cleared by the FDA for commercial use (most of the 40,000 POLs which do non-waivered testing are moderate complexity); and gave laboratories additional time to meet applicable quality control requirements for commercial, nonmodified tests; and announced approval of the American Society of Clinical Pathologists (ASCP) as a certifying organization for cytotechnologists, which affects 10,000 individuals.

In addition, another CLIA regulation is currently under review that will add three new PPM tests (moderate complexity tests that can be performed without regular inspections); includes new personnel that may perform PPM tests (midlevel practitioners and dentists); and, grandfather certain high complexity personnel performing high complexity testing.

When this regulation is published, midlevel practitioners and dentists, physicians who currently perform PPM testing who wish to expand testing, and high-complexity testing personnel employed before CLIA will be positively affected. In addition, there will be a positive impact on medically underserved areas because of the increased availability of testing and personnel qualified under CLIA to perform that testing. These changes may affect as many as 5,000 to 10,000 laboratories.

GENERAL POINTS FOR CONSIDERATION:

- CLIA allows for the privatizing and decentralizing of laboratory monitoring by allowing laboratories to achieve compliance through accreditation by private accrediting organizations and by CLIA-exemption of laboratories in States with similar licensure laws. Approximately 20,000 accredited laboratories voluntarily comply with the more stringent standards of approved private organizations.

- CLIA is customer focused. Surveys are educational. Professional laboratory and medical organizations agree that actual HCFA surveys are less fearsome and burdensome and more educational than expected and are promoting their benefits. Approximately 40,000 surveys are performed biennially.

- An announced survey policy has been implemented with over $1M savings per year. No sanctions have been imposed for the first survey cycle for previously unregulated laboratories (unless serious risk to patient health).

- A CME program has been developed for physicians to meet personnel qualification requirements as laboratory director.

- A Non-Onsite Survey Protocol is being developed as an alternative to the onsite survey process for selected laboratories. This affects 1,000 laboratories now; however, if utilized as a reward for exceptional survey performance, this could affect 5,000 laboratories.

HMO Organizational Structure and Services

A HCFA regulation will provide organizations that operate HMOs that are federally qualified under title XIII of the Public Health Service Act with greater flexibility in operating other health benefit plans. The proposed rule was published on July 15, 1993. This proposed rule would also authorize, with certain limitations, federally qualified HMOs to offer out-of-plan physician services and require a reasonable deductible for those services. Further, this regulation would permit the HMO to use assets of the parent organization to meet fiscal soundness and insolvency protection requirements. The HMO final rule is scheduled to be published in 1995 and will have no budget impact.

Flexible Employer Contributions to HMOs.

A final HCFA regulation is being developed that will provide employers with increase flexibility in determining their contribution for employees enrolled in Federally Qualified HMOs. The rule implements more liberal contribution requirements, and gives employers the latitude to develop appropriate contribution methodologies.

Revising Provider Conditions of Participation

HCFA promulgates conditions which must be met for providers to participate in the Medicare program. In some cases, conditions of participation for Medicare providers have not been modified since the inception of the program in 1965 and are sorely in need of refinement to adapt to technological changes in the delivery of care. HCFA is in the process of revising the conditions of participation for hospitals, end stage renal disease facilities, and home health agencies to make them more easily understandable, outcome-based, and less process-oriented. The revised conditions of participation will affect over 6,000 hospitals. The revised conditions of coverage for ESRD facilities affect 731 hospitals that have dialysis units and 1,795 free standing facilities. Finally, there are 7,200 home health agencies that would be beneficially impacted by the new conditions.

"B" List
1/27/95

HCFA RESPONSES TO COMMENTS ON CURRENT STATUS OF THE HEALTH SECTOR REGULATORY REFORM DOCUMENT ?

NEED FOR THE MEDICARE PEER REVIEW PROGRAM

SUMMARY:

Should the government be supporting the Peer Review function given the limited utility of the reviews conducted by these organizations and the substantial emerging market in private utilization review and case management?

RESPONSE:

HCFA recognized that the monitoring of individual medical records by Peer Review Organizations (PROs) was not the most advantageous means of improving the quality and effectiveness of medical care provided to the Medicare beneficiary population.

In place of case review, Peer Review Organizations are working with their local health care communities to identify and interpret scientifically sound parameters of practice to measure quality of care. Using statistical quality surveillance to examine variations in the processes and outcomes of care, they share the resulting data with plans, providers and physicians, to work with them to improve care. In doing this, the privacy of individually identified information is always maintained.

We believe this function is a key responsibility of Medicare as a purchaser of health care for Medicare beneficiaries. PRO work to date demonstrates substantial opportunities for improvement and positive responsive action from hospitals and physicians. For example, PROs are working with hospitals in four states because Medicare data revealed quality problems in the care of patients hospitalized with acute myocardial infarctions. Data revealed that many patients were not benefitting from proven therapies. Early reports suggest that over 50 percent of hospitals working with the PROs are examining new ways to improve care for these patients. Similarly, drugs such as aspirin and warfarin have been shown to reduce the risk of stroke in patients with atrial fibrillation. One PRO, identifying the fact that less than half of the patients in its state were receiving such medication upon discharge, is working with almost all of the hospitals in its state to assess and improve their performance in treating these patients.

The PRO contribution here is unique. It abstracts and analyzes clinical data from the large Medicare data base, studies patterns, identifies opportunities for improvement and presents the data to hospital staff for their analysis and use. This is of tremendous asset to the hospital in its quality management program. In this way, valuable benchmarking data, not otherwise

obtainable, is provided to physicians. Such widespread cross-institutional information is just not available anywhere else.

OWNERSHIP AND REFERRAL LAWS

SUMMARY:

The physician referral issue is one of over-utilization, and we should be regulating for that problem generically, not through the onerous and somewhat arbitrary rule structure driven by current law. There should be an outside certification approach linked with heavy penalties for clear over-utilization linked to financial interest. This restructuring should be linked to the PRO restructuring.

RESPONSE:

When a patient seeks medical care, his or her physician has a major role in determining utilization of services furnished to the patient by other health care providers and suppliers. The physician evaluates the patient, orders diagnostic tests, and decides upon the appropriate medical care and any needed therapy for the patient. Having a financial interest in a provider or supplier of services can affect the physician's decisions. In fact, studies performed by the OIG, GAO, and non-government groups have concluded that physicians who have financial relationships with health care providers and suppliers tend to refer their patients to that entity more frequently than other physicians. In effect, these studies have demonstrated that physician self referral serves as an effective proxy for over-utilization of services.

In the future, truly integrated systems (that is, systems jointly owned by hospitals and physicians that are organized to provide a continuum of care) will make decisions about individual patients at the caregiver level, but decisions about resource allocation and strategic planning will be made by the network. Generally, integrated systems look at competition and incentive structures by developing ways to reward staff for helping reach the goals of integrated delivery: high quality, lower-utilization, cost effectiveness, and closely monitored patient, staff and payer satisfaction. We agree that once integrated systems are more common, there may be a better solution to the problem of over-utilization of services, but at this time it appears that this type of system would not solve the physician self-referral problem.

In 1993, carriers were required to establish an infrastructure to implement Focused Medical Review (FMR). In 1994, as part of their FMR efforts, carriers were required to develop methods to profile physicians' ordering and referring patterns. In 1995

carriers will be required to evaluate the impact of these patterns. To implement FMR, carriers are expected to develop computer systems and methodology to analyze claims and then find the most effective course for resolving problems which result from inappropriate practice patterns. We believe that, while our current priority must be to implement the physician self-referral law, over time that utilization information should be used to determine whether additional regulatory measures that would further limit the exceptions are required.

REIMBURSEMENT MECHANISMS

SUMMARY:

Review arbitrary constraints in the systems and reform certain Medicare coverage and payment rules which may impede the provision of lower cost care. Several policies were cited that warrant review.

RESPONSE:

The Health Care Financing Administration (HCFA) is continuously engaged in an ongoing process of reviewing and evaluating coverage and payment policies to ensure the most efficient delivery of quality services to Medicare beneficiaries. We share the desire to identify and correct Medicare rules which present arbitrary constraints or unwarranted prohibitions on the efficient and effective provision of care. However, we note that many constraints which appear at first to be arbitrary constitute significant utilization controls. The removal of such provisions could result in notable increases in Medicare expenditures. For example, the repeal of the three day prior hospital stay requirement for Medicare coverage of skilled nursing facility services by the Medicare Catastrophic Coverage Act resulted in a dramatic increase in skilled nursing facility expenditures in 1989. Therefore, we urge a careful evaluation of all reform proposals to guard against unintended increases in Medicare outlays.

We have the following comments on the examples specifically cited:

> **Telemedicine** -- Medicare does not currently cover telemedicine. HCFA is conducting several demonstration projects on telemedicine and will be deciding FY '95 grant applications over the next several months. We believe that additional research is necessary before policy decisions are made.
>
> **Hospice and Long Term Care** -- The HCFA Long Term Care Workgroup, in cooperation with staff from throughout the

Department of Health and Human Services, is actively evaluating the long term care needs of Medicare and Medicaid beneficiaries. Included in this effort is the evaluation of the Medicare hospice, skilled nursing facility, and home health benefits. A primary goal of this effort is to develop the extent to which these benefits meet the long term care needs of Medicare beneficiaries and to develop improvements to the Medicare and Medicaid program so that needs such as those described in the OMB comments can be better met in an efficient manner. The Workgroup is currently examining a variety of options to meet this goal.

Reimbursement Rates for Outpatient and Inpatient Care -- The prospective payment system for hospital inpatient services is intended to capture justifiable cost differences. Payment for hospital outpatient and skilled nursing facility services is currently cost-based. Variation among payments for hospital inpatient services, hospital outpatient services, and skilled nursing facility services would likely be reduced by the development of prospective payment systems for hospital outpatient and skilled nursing facility services. HCFA is currently exploring the development of such payment systems.

OVERLAPPING JURISDICTION

Not applicable to HCFA.

Department of Labor Issue

VARYING SURVEY REQUIREMENTS

SUMMARY:

Streamline NIOSH, CDC, HCFA and FDA survey activities and ensure that requirements for all are compatible and do not put facilities at an economic disadvantage. For designated facility-types, pilot efforts to accomplish this goal.

RESPONSE:

HCFA supports the concept of consolidating similar or duplicative survey requirements and processes into logical and functional units in order to streamline these activities as well as to provide relief to providers which are inspected by numerous entities over time.

Conceptually, this effort at streamlining would begin by identifying which laws and regulations spread across the executive branch provide opportunities for consolidation into single authorities for quality assurance monitoring and enforcement purposes. For example, all infection control authorities in HCFA and OSHA might logically come under one inspection process. The next step would be to identify the skills and resources necessary to be brought together, in partnership with State and local health authorities, to make a streamlined process work. The third step would be to conduct a pilot project to test the feasibility, efficiency and efficacy of consolidating these functions.

A major consideration in this proposal is the widely varying statutory bases for all of the programs which might be included in this effort. Gaining statutory flexibility would be essential.

OTHER CLIA ALTERNATIVES

SUMMARY:

Alternative 1

Should be on A list

Repeal part of the statute, eliminating a significant portion of the personnel, quality control and quality assurance requirements with the exception of cytology.

RESPONSE:

These portions of the statute should be retained. We have made recommendations to accommodate concerns that such requirements are burdensome; however total elimination of these requirements would have an adverse impact on laboratory services and their use. The proposal suggests relying solely on proficiency testing (PT) to ensure quality. The PT process has limitations and is subject to some level of error itself. PT alone cannot assure quality of performance. Data is being collected which indicates that significant numbers of lab tests do not yield accurate results.

SUMMARY:

Alternative 2

Use quality indicators and/or performance standards with outcome indicators (e.g., proficiency testing) and remove the process and personnel requirements

RESPONSE:

We agree that quality indicators and/or performance standards are desirable and useful. However, PT has many inherent problems, and as a result good laboratories may perform poorly and poor laboratories well. We believe that PT by itself will not be acceptable by the laboratories.

We are just beginning to develop these performance standards, but it is not apparent which might be useful. Baseline information is needed to determine which specific quality indicators would be most appropriate to evaluate the quality of laboratory services in the least intrusive manner. Providers of laboratory services are extremely varied and diverse. Therefore, the challenge of designing and implementing these standards or a similar process would require considerable time and the outcome is uncertain.

MOVEMENT TOWARDS PERFORMANCE MEASURES IN HEALTH OUTCOMES

SUMMARY:

As performance measures of health outcomes are developed, evaluate the continued need for oversight and regulation of each segment of the marketplace.

RESPONSE:

The growing availability of performance indicators in the health care arena affords many opportunities to recast many health care regulations, such as home care, dialysis and nursing homes, among others. The trend in health care is clearly toward less prescriptive requirements and over time, performance indicators will hasten that change. HCFA does not believe that this proposal changes anything about our current direction. We support its basic thrust. However, the reliable use of performance indicators in surveillance systems is still years away, as the work to develop, test and implement them is extensive.

The use of performance indicators will change the nature of oversight but will not eliminate it. Performance indicators do not replace the importance of actual, onsite inspection of providers, particularly to investigate complaints, determine initial eligibility and validate the accuracy and reliability of the performance indicator data being supplied.

1. Done
2. Now
3. Underway
4. ?
5. Can't be done until Natl Elig. file est.
6. Vol - not all 50 states, being implemented
7. Underway

1. Stn scope
2. ?
3. Not Relevant
4. done
5. done
6. done
7. done
8. done ?

Black box waiver bec quality
Blank test prev. test prof.

→ 1. Taken 1 step but haven't finished
2. Not been done -
3. Now - targ. bec. of quality
4. done
5. ~~Now~~ Now

1. Now - leg. flex. in survey
2. Underway - now
3. Patients to monitor own dialyses

Comments on current status of the health sector regulatory reform document:

A number of regulatory programs that have a significant impact on the health sector will not be raised in the initial meeting. These programs should be listed in an appendix or addendum with brief descriptions and the commitment to develop options in each program area if the Vice President so desires. The programs that need such descriptions are as follows:

- The PRO program i.e., Physician Review Organizations - HCFA argues that this has just been revamped which is true, but there are legitimate questions as to whether the government should be in this business particularly given the limited utility of the reviews and the substantial emerging marketing in private utilization review and case management.

- Ownership and referral laws, i.e., programs targeted at kickbacks and over-utilization of services that prohibit patient referals to facilities in which a physician has a financial interest. Although there is evidence to support the notion that some physicians abuse testing and treatment referrals due to their financial interests, many physicians over-utilize regardless and the requirements only apply to arms length relationships and not vertically integrated delivery systems. The issue is over-utilization and we should be regulating for that problem generically not through the onerous and somewhat arbitrary rule structure driven by current law. We could have an outside certification approach linked with heavy penalties for clear over-utilization linked to financial interest. This restructuring should be linked to the PRO restructuring.

- Reimbursement mechanisms - although taking on the entire structure is probably much too close to health care reform, there are many arbitrary constraints in the systems and certain prohibitions that could significantly reformed, particularly those that may impede lower cost care for which HCFA does not reimburse. Some examples include: telemedicine care that is limited to reimbursement for the equivalent of a face-to-face encounter, immediately undermining some of the savings that could result from less intensive interactions; the definition of hospice whi restricted to faciltiies treating individuals in the months of life, while certain longer term acute recov might benefit from such lower intensity care; and, variations in reimbursement rates for identical outpa and inpatient care. Decisions on revised reimburseme not easy and the solutions can bring their own complications, but this area does warrant review.

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that could be characterized as overreacting to the AIDS fear. We could also argue that now that the practices have penetrated the work place the detailed regulation may not be necessary and we should come up with a more targeted approach. This rule also conflicts with the public health message we try to deliver about working and living with people with AIDS, e.g., gloves and masks for any and all exposures to bodily fluids when we assure people that nominal exposure is not really a risk. Concentrating on needle sticks and substantial exposure to blood may be desirable.

- Varying survey requirements or varying surveyors. NI CDC, HCFA and FDA could conceivably inspect the same institutions for similar or related aspects. Streaml these activities and ensuring that requirements for multipurpose facilities are compatible and do not put facilities as an economic disadvantage should be the Given the number of programs and multiple purposes th of activity may need some pilot efforts on the part o facilities and the various Federal agencies.

Pursue this

- Other CLIA alternatives - Partial repeal, eliminate a significant portion of the statute including personnel requirements and the quality control and quality assurance requirements with the possible exception of the cytology requirements that generated the main impetus for the statute. It is unclear whether Congress or the agency is likely to go for this although some of the new repub may try to push for it. Another alternative is to r the statute to give more flexibility to the Secretar waive the process and personnel requirements in thei entirety when adequate performance standards are in rather than only when you are dealing with waived te i.e., tests that will only incur negligible risk. H asserts that performance testing is not possible due cost and complexity of blind testing. There is anot possible option of look behind proficiency testing already performed that could be explored. An impor fallacy in goal of the statute is the level of prec testing. Although some tests are precise, many are not. The goal of precision rather than best practices could be considered.

Why CLIA not sig. Des?

- As we move toward performance measures in health outcomes, we should consider whether there is a continued need for oversight and regulation for each segment of the marketplace. The regulation of each segment often creates unintended effects including the emergence of new segments due to the cost of regulation in existing facilities, e.g., home care, adult day care, board and care homes. Many of these services and entities are not intended for health care per se and should not necessarily be the purview of Federal regulation. Alternatively we should assess the extent to

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- As we move toward performance measures in health outcomes, we should consider whether there is a continued need for oversight and regulation for each segment of the marketplace. The regulation of each segment often creates unintended effects including the emergence of new segments due to the cost of regulation in existing facilities, e.g., home care, adult day care, board and care homes. Many of these services and entities are not intended for health care per se and should not necessarily be the purview of Federal regulation. Alternatively we should assess the extent to

Why CLIA not sig. Acs?

which the possible overregulation of existing facilities has created a less than satisfactory set of service alternatives.

Regarding the options that HHS has put forth the boldest are the preformance standards in lieu of prescirptive standards of participation. The ability to waive the prescriptive requirements, however, needs to come in tandem with adherence to performance standards otherwise we're simply adding another layer of regulation. We would need to seek the necessary legislative change simultaneously with the regulatory changes. The CLIA standards are likely to be viewed as marginal albeit streamlined rules. They have also been in the pipeline for sometime and will not necessarily be view as very bold.

They're only doing this for a subset of negligible risk tests. They say can't do pt. stds for more complicated tests.

Aside for internal discussion only - OIRA has an ongoing concern with the revised CLIA rules because ofthe possible duplicative review of diagnostic devices between FDA and CDC. Originally FDA was going to perform the device assessment of diagnostic devices that are waived or simple, i.e., the emerging technology that automates the test to remove human error. FDA now wants CDC to perform the categorization and determination as to whether it meets quality assurance and control requirement under CLIA. We are still hard pressed to understand how this determination significantly differs from FDA's review. We are however somewhat persuaded that CDC may be much more expedient and in time could be the better oversight agency for diagnostic devices.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

Executive Secretariat

1-12-95

FACSIMILE

PLEASE NOTIFY OR HAND-CARRY THIS TRANSMISSION TO THE FOLLOWING PERSON AS SOON AS POSSIBLE:

NAME: Jennifer Kline

ADDRESS: _____

_____

TELEPHONE NUMBER: _____ FAX NUMBER: 456-2878

MESSAGE: _____

_____

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FROM: Claudia Cooley

TELEPHONE NUMBER: 690-5627 FAX NUMBER: 690-7203

DRAF

PROBLEM	REGULATORY APPROACH	PROPOSED SOLUTION	PROS & CONS	ALTERNATIVES NOT SELECTED	WHY NOT SELECTED
HEALTH AND SAFETY STANDARDS FOR MEDICARE PROVIDERS					
1. Hospitals, home health agencies (HHAs), hospices, and End-Stage Renal Disease (ESRD) facilities must meet health and safety requirements to participate in the Medicare program. These requirements are "process" oriented (i.e., use procedural and administrative requirements as proxies for quality health care) rather than "outcome" oriented (ie., evaluate actual patient care) and continuous quality improvement.	Use of performance standards. (Outcomes)	Revamp Medicare participation requirements to focus on outcomes and to include the collection and analysis of patient care data necessary for continuous quality improvement and performance evaluation.	Pros: Eliminating proxy measures for compliance could ~~mitigate~~ lessen compliance and survey burdens. Eliminating process requirements will make it possible to focus on actual patient care. Cons: Elimination of process requirements could be viewed by patient advocates as the elimination of patient safeguards. Development of data requirements could be viewed as additional burden in home health agencies.	N/A	N/A
2. 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.	Flexible survey schedules related to performance.	Seek an amendment to Section 1891(c)(2)(A) of the Social Security Act to allow flexible survey schedule for HHAs.	Pros: Law currently allows flexible surveys for all providers except HHAs and nursing homes. Will save the industry and the government an estimated $10 million. Cons: Some out of compliance HHAs may fall through the cracks under a flexible system.	Seek flexible survey cycle for nursing homes.	Current nursing home survey cycle allows some discretion (i.e., allows a maximum of 15 months between surveys for a given home while requiring a 12 month average for each State). Greater flexibility would be inappropriate due to the vulnerability of the nursing home population, generally low level of professional supervision, and historical problems.

Shannah — tie these together
— allover waivers
→ Consumer watchdogs

PROBLEM	REGULATORY APPROACH	PROPOSED SOLUTION	PROS & CONS	ALTERNATIVES NOT SELECTED	WHY NOT SELECTED
PHYSICIAN ATTESTATION					
Physicians must sign "attestation" certifying accuracy of diagnoses/ procedures for all hospital admissions under the prospective payment system, causing huge burdens and costs for physicians and hospitals. Also, costly for resource-strapped Peer Review Organizations to monitor.	Lower burden.	Eliminate current regulations' requirement for physician attestation and hold hospitals responsible for accuracy. (HCFA will soon meet with OIG and DOJ.)	Pros: Physicians and hospitals will like. Attestation requirement appears obsolete - never prosecuted & DRG/coding complexities, not understood by physicians, make requirement inappropriate. Decrease in administrative costs to hospitals. Cons: Lack of prosecutions so far does not preclude future ones, which would be aided by attestations. Despite coding/DRG complexities, physicians viewed as most knowledgeable on care given to hospitalized patients.	N/A	N/A

DRAFT

The Problem	Regulatory Approach	Proposed Solution	Pros and Cons	Alternatives Not Selected	Why Not Selected
CLIA					
1. CLIA is unnecessarily burdensome (especially for small POLs) due to broad scope and "one size fits all" approach.	Make greater use of waivers.	Revise regulation to expand criteria for waived tests. Solicit applications from manufacturers for waived tests. FDA OTC approvals are automatically waived, if requested by manufacturers.	Increase access to greater variety of tests. POLs may expand test menus without an increase in costs/burden. Encourages better technology. Oversight of waived tests for complaints only. Can be used as marketing and fiscal tool for manufacturers. This change will make POLs happy.	Maintain current waiver criteria.	Public and lab community expressed objections to current criteria as being too subjective and the difficulty of approving additional tests under present criteria.
				Automatic waiver of tests proposed in Archer amendment.	Waivers should meet specific criteria to avoid causing irreparable harm.

The Problem	Regulatory Approach	Proposed Solution	Pros and Cons	Alternatives Not Selected	Why Not Selected
1. (Cont'd)	Re-engineer current regulations to reduce oversight of labs using improved technology	Reduce oversight of users of "black box" (accurate and precise--APT) by instituting a new category of certification (APT) with fewer requirements.	Reduce burdens/ costs. Eliminates routine surveys. Decreases regulatory burden for POLs. Encourage market place driven technology. Less oversight and monitoring of quality in POLs.	Do not recognize "black box" technology by creating new testing category. Waiver of "black box" technology.	Not recognizing new technologies may impede technological progress. Inappropriate waiver of test syst may cause irreparable harm to public.

The Problem	Regulatory Approach	Proposed Solution	Pros and Cons	Alternatives Not Selected	Why Not Selected
2. Labs fear sanctions for proficiency testing (PT) failures.	Emphasize information and education rather than sanctions.	Use PT "failures" for education and as an outcome indicator in laboratory quality not for punitive action. Continue use of educational focus in survey process.	Reduce anxiety in the POL community while maintaining opportunity for POL selfassessment. Education is a positive approach; customer-focused. POLs do not consider participation in PT cost effective. Data indicates PT facilitates improved quality performance. POLs are happy with these solutions.	No longer require PT.	PT is a valuable outcome indicator and educational tool. PT participation required by statute.

Not a reason — we can suggest statutory change

The Problem	Regulatory Approach	Proposed Solution	Pros and Cons	Alternatives Not Selected	Why Not Selected
3. Surveys are burdensome to the laboratory.	Performance standards and flexible survey schedules. Utilize deemed status.	Require less frequent surveys of excellent performers. Approve accrediting organizations for deemed status and approve state licensure programs for CLIA exemption.	Reduce the survey burden. Reward good performers with fewer surveys. This would be a positive incentive to improve performance.	Status quo	Need to reduce burden.

ıe Problem	Regulatory Approach	Proposed Solution	Pros and Cons	Alternatives Not Selected	Why Not Selected
. (Cont'd)		Utilize flexible survey protocol. Utilize outcome indicators. Implement APT category. Implement survey efficiencies.	Educational emphasis has generated a positive response from the previously unregulated laboratory community. Approving organizations for deemed status offers laboratories oversite by peers.		

DEPARTMENT OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

Executive Secretariat

FACSIMILE

PLEASE NOTIFY OR HAND-CARRY THIS TRANSMISSION TO THE FOLLOWING PERSON AS SOON AS POSSIBLE:

Name: Allison Eydt

Address: _____

_____

_____

Message: If you want to discuss some of the specifc wording you may talk with Cam Gardett of the HHS press office at 690-6343. Let me know if you clear this so that we can release the regulation.

Telephone: Office: _____ FAX: _____

Number Of Pages Being Transmitted (Including This One) 3

FROM: Anna Boyd, Executive Secretariat, HHS

FAX NUMBER: 690-7203

OFFICE NUMBER: 690-6111

HHS NEWS

DRAFT #40

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE

Contact: Anne Verano
(202) 690-6145

The Health Care Financing Administration today reduced a paperwork burden on physicians by eliminating the need for doctors to file an annual statement with the hospitals to which they admit Medicare patients.

"This change will reduce a bureaucratic hassle that the Medicare program had placed on physicians," said HHS Secretary Donna E. Shalala. "This is the type of streamlining that will result from the President's health care reform program."

The new rule, published in today's Federal Register, will go into effect in 30 days. It will require physicians to sign a document, known as an acknowledgement statement, only once when they are originally granted admitting privileges to a hospital.

Some 300,000 physicians and 6,000 hospitals are affected by the rule.

"Physicians and hospitals have had problems meeting the requirements of the old rule," said HCFA Administrator Bruce C. Vladeck.

Attending physicians must attest to the diagnoses and procedures performed on patients before they can submit Medicare claims. This arrangement ensures that the information used for claims payment is correct.

As a part of the current requirement, hospitals are required to obtain annually from each attending physician, a signed

- More -

DRAFT

#40

acknowledgement that the physician understands the penalty for misrepresenting, falsifying or concealing essential information required for claims payment.

This physician acknowledgement must have been completed within the year prior to submitting the claim.

The new rule eliminates the requirement for the annual statement. Instead, physicians will read and sign the document once at each hospital where they have admitting privileges.

"Physicians and hospitals told us the old rule increased costs, took too much time and added to the heavy paperwork burden," Vladeck said. "They did not believe the cost and burden added value to the process. This change alleviates that problem."

Because of its commitment to reduce the administrative burden on physicians and hospitals as soon as possible, HCFA waived the notice of proposed rulemaking and, in this instance, issued a final rule immediately. Public comments on the rule will be accepted for 60 days.

HCFA is the federal agency which administers the Medicare and Medicaid programs that help pay the medical bills of 67 million Americans. HCFA's estimated fiscal year 1994 expenditures will total more than $250 billion.

# # #

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

05-Jan-1995 05:17pm

TO: Jennifer L. Klein

FROM: Shannah Koss
Office of Mgmt and Budget, OIRA

SUBJECT: HHS reg ideas

Health regulation

→ CLIA - provide a real performance standards alternative

Link regulatory oversight to performance for all facility regulation and review. Use regulatory burden or the lack there of as an incentive.

→ Survey and certification - move to performance based audit and review cycle - eliminate all fixed review cycles.

Revise reporting and recordkeeping requirements for providers and facilities

Revised reimbursement to enhance competition

Overlapping jurisdiction and regulation

Bloodborne pathogens rule (OSHA) vs. CDC universal precautions -is this level of regulation necessary given the risks.

Adverse reporting mechanisms for FDA and HCFA, i.e., requirements for facilities

DUR counseling and the upcoming medguide regulation

FDA and CPSC - should certain low risk responsibilities be shifted?

Generic ways to rethink FDA regulation

FDA oversight is largely a question of improving health by reducing health risks and approving products intended to improve health.

All of its regulatory programs are risk based and require risk-benefit determinations as to whether something should be allowed into the market or removed. [gatekeeper vs. exorcist]

→ For drugs and devices FDA's scheme is predominantly a gatekeeper scheme and allows very little risk into the market place. For lower risk product categories and for higher risk products where there are no adequate alternative therapies a shift away from prior approval toward post-market surveillance could be considered. For certain categories of "devices" FDA should consider getting out of the business altogether e.g., external generic use products.

In the few areas where FDA regulates facilities (mammography, blood banks, tissue banks) - movement toward performance standards rather than command and control quality standards should be explored.

In the areas of foods and cosmetics FDA could move as completely as possible to post-market surveillance and rely more heavily on market-based solutions. Certain regulatory models are outdated and could be eliminated e.g., standards of identity for foods, certain electronic product requirements.

Various FDA drug approval ideas

Privatize approval more of a European model, like certain standards bodies, e.g., electronic standards.

Expanded use of IRBs

External review/Contract out - Mitre initiative

Revised risk-risk trade offs - earlier approval with enhanced phase 4 trials or enhanced post-market surveillance.

Greater flexibility for non-commercial INDs or some experimentation in the context of contained health care delivery models (combine greater flex with enhanced PBM, management and surveillance).

More reliance on buyer beware - full disclosure on risks and benefits and level of uncertainty, less emphasis on efficacy

Harmonization/reciprocity with certain advanced medical countries

Enhanced use of over-the counter

Questions about the status of current activities:

? Mitre pilot
? Parallel track
? Fast track approval/phase VI
? Surrogate endpoints - CF anecdote surrogate not sufficient
? Moving beyond cancer and AIDS
? Approval times - before and after user fees
? Off label uses, combination therapies, pediatric labeling, CME - all apparent increases in regulation

Status of Orphan drug development - has the incentive lost its power?

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

05-Jan-1995 05:19pm

TO: Jennifer L. Klein

FROM: Shannah Koss
Office of Mgmt and Budget, OIRA

SUBJECT: HCFA regs ideas

Allison Eydt from my staff put this together yesterday and sent it to HHS. I haven't look at it too closely, but hopefully it helps.
HCFA Regulation
Thematic Areas for Improvement

Problem: Controlling Utilization and Federal Expenditures at the Expense of Access Because the Medicare and Medicaid programs are on-budget, some regulation is necessary to ensure that beneficiaries/recipients and providers utilize only services that are reasonable and necessary. In the past, however, HCFA inappropriately has used burdensome regulations focused on quality of care to control utilization and expenditures. These costly, "process" regulations (e.g. personnel credentialing, reporting, and recordkeeping, etc.) may discourage beneficiaries/recipients and providers from consuming health services. These regulations not only shift burdens onto the private sector, but by limiting access to services, they can have a negative impact on health outcomes and quality of care in the long run.

Example Area for Improvement: Regulation of physician office laboratories and "waived" tests pursuant to the Clinical Laboratory Improvement Amendments of 1988.

* * * * *

Problem: "Process" versus "Performance-Based" Regulation: Facility regulations should incorporate performance measures such as patient outcomes and rely less on process requirements such as personnel requirements, recordkeeping and reporting.

Example Area for Improvement: Pursuant to OBRA '87, HCFA must enforce numerous prescriptive personnel and physical plant requirements for nursing homes (and home health agencies.) HCFA has been creative in its final enforcement rules for nursing homes, but was restricted from moving entirely toward outcome-based regulation by detailed, process requirements

articulated in statute.

* * * * *

Problem: Provider-Specific Quality of Care Regulation and Reimbursement: The regulations should be flexible in design so they can withstand changes in the health marketplace. They should not vary by site of care (e.g. hospital outpatient department versus ambulatory surgical center.) As the health care market becomes more diverse and fluid, the artificial definitions associated with facilities will become obsolete. Regulation and reimbursement based on facility designation exacerbates special interest lobbying and may not enhance patient outcomes or program effectiveness.

Example Area for Improvement: The entire Medicare program is regulated by provider type; most of the methodology is articulated in statute.

Problem: Inflexible, Rigid Enforcement Strategies: Enforcement approaches should depend more on past compliance history and at a minimum, be targeted to areas of greatest, imminent risk to patient health and safety. For example, survey frequencies should vary depending on a specific facility's compliance history, e.g. a shorter cycle for facilities with poor compliance in health outcome requirements and a longer cycle for facilities in full compliance.

Example Area for Improvement: In its final nursing home enforcement rule, HCFA made progress in relating enforcement remedies to a facility's compliance history and the nature of its noncompliance (e.g. compliance in "process" versus quality of care standards.) HCFA, however, could not vary the survey cycle for facilities based on past compliance because OBRA '87 narrowly defines an allowable survey cycle (a maximum 15 months between surveys for each nursing home and a statewide survey cycle average of 12 months.) This provision has limited HCFA's flexibility in providing cost effective incentives for superior performance in nursing homes.

* * * * *

Problem: Regulation that Creates and Protects Jobs, but May Not Improve Quality of Care : Related to the above "performance" recommendation, regulations should not carve out a niche for a particular industry or professional group but should encourage competition between entities to capture the maximum health outcomes for the dollar.

Example Areas for Improvement: Pursuant to the Social Security Act, the Joint Commission on the Accreditation of Health Organizations (JCAHO) has a monopoly over private accreditation of hospitals. This competitive void eventually may have a negative impact on hospital private accreditation and health care services provided by deemed status facilities. An example of "guild group" regulation is the OBRA '87 nursing home provisions mandating RN staffing levels. The nurse staffing provisions were the most costly, regulatory provisions (almost $100 million/fiscal year).

* * * * *

Problem: Redundancy between Enforcement Programs: Enforcement approaches should be consolidated and redundant programs eliminated to minimize Federal intrusiveness upon private sector entities.

Example Area for Improvement: The Peer Review and Utilization Review program may be redundant with activities conducted under hospital survey and certification.

* * * * *

Other approaches to cost effective, least burdensome regulation:

Information Sharing in lieu of Frequent Onsite Visits : A common argument against lengthening survey cycles has been that it is difficult for the enforcement agency to stay on top of developments that could impinge upon quality of care between visits. In addition, reliance on surveying patient outcomes is reactive, and does little to prevent adverse outcomes from occurring in the first place. Information dissemination and feedback loops can be used in lieu of frequent onsite monitoring by survey teams. Such information could provide assurance that the level of care has not decreased significantly since the last survey. Troublesome trends in facilities could trigger surveys earlier than originally scheduled and offer stronger incentives for ongoing facility compliance. Information should reside at the entity or local level until requested on a "validation" or "look-behind" basis.

* * * * *

Information Dissemination and Consumer Enpowerment: Information on facility performance in surveys should be widely disseminated to the public so it can be used in selecting providers.

Area for Improvement: At one time, HCFA published results of its nursing home surveys, but has discontinued this practice. HCFA also has discontinued publication of hospital mortality statistics.

Pass out:

- List of other groups
- our group
- cross cutting paper

Mike Taylor - Agriculture

Goals

As you know, the Vice President is initiating a bold regulatory reform effort. As I have mentioned to several of you on the phone, we have been instructed to make recommendations in three broad areas:

1. Be bold, innovative and "outrageous" -- such as moving to market incentives such as voluntary regulatory structures, streamlining agency responsibilities, increasing waiver authority, fostering regulatory simplicity including one-stop shopping and single forms for a series of regulations, and establishing a presumption against issuing new regulations.

2. Develop a "customer service" oriented approach to regulation -- consider working with those who are being regulated and those who we are trying to protect.

3. Identify and review areas of overlapping jurisdiction, conflicting statutory requirements.

Timetable

Current schedule

- Food and Drugs -- January 31 (scheduled with consumer product safety)

- Health industry regulation -- February 2

Product

Given the short timeframe, we cannot look at all areas of health regulation nor can we do a regulation-by-regulation review. Instead, we should come up with two or three areas that are particularly controversial or burdensome and develop new models for regulation in those areas.

This meeting -- brainstorm about what those areas are.

Next meeting -- probably Friday -- within the areas we have decided to focus on, bring a list of problems/obstacles within the areas we have chosen to focus on and a list of options (from moderate to bold) for solving these problems.

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a publication.

Publications have not been scanned in their entirety for the purpose of digitization. To see the full publication please search online or visit the Clinton Presidential Library's Research Room.

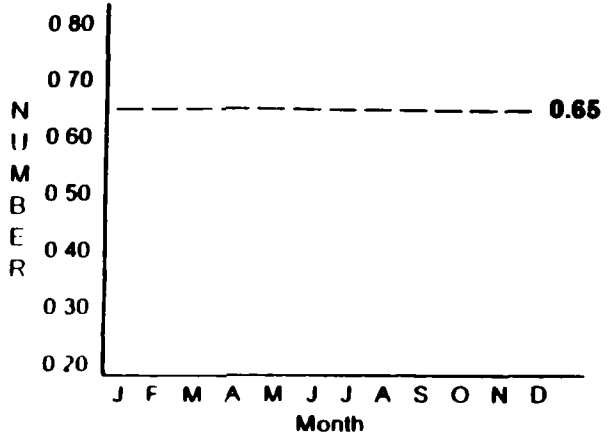
Pamphlet, "It's Your Life... Know Your Number," 2 pages

- **Ask your dialysis nurse or your doctor for your test *number*.**

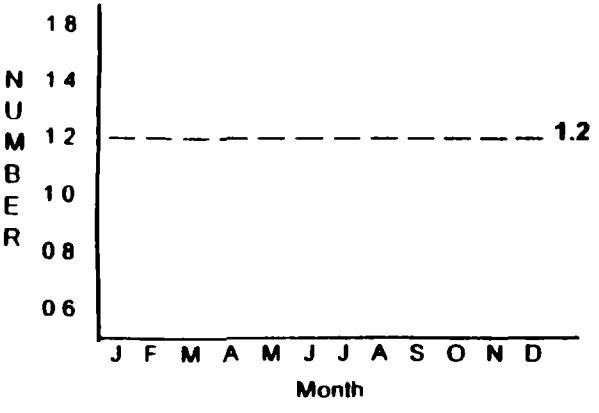
- **Put an X to show your test *number*.**

- **If your X falls below the dotted line, talk to your physician.**

For Urea Reduction Ratio (URR) Test



For Kt/V Test



It's Your LIFE...

Know Your NUMBER!

A Guide to an Important Test for Dialysis Patients

U.S. Department of Health and Human Services
Health Care Financing Administration

WHAT IS THIS *NUMBER*?

The *number* is a blood test result. There are two types of blood tests to measure the amount of a waste product, called urea, in your blood.

These tests are:

Urea Reduction Ratio (URR)
Kt/V

If you have too much urea in your blood, it can make you feel sick to your stomach, tired, or give you loose bowel movements.

WHY IS MY *NUMBER* IMPORTANT?

Dialysis acts like your kidneys by removing waste products from your blood. Your *number* tells you how much less urea is in your blood after dialysis. It tells you how well your dialysis treatments are working. People with less urea in their blood feel better and live longer.

WHAT SHOULD MY *NUMBER* BE?

If your dialysis center uses the URR test, your urea should have gone down by 65 percent (0.65) or more after your treatment.

If your dialysis center uses the Kt/V test, your *number* should be 1.2 or above.

Your dialysis staff can give you more information on these tests.

HOW CAN I FIND OUT WHAT MY *NUMBER* IS?

Your nurse or doctor at the dialysis center can give you your *number*. You may want to write down your *number* on the URR or Kt/V chart on the back of this pamphlet.

If your URR *number* is less than 0.65 or your Kt/V *number* is less than 1.2, talk to your doctor about how to improve your dialysis.

ARE THERE OTHER *NUMBERS* I NEED TO KNOW ABOUT?

There are many tests done for you at the dialysis center. However, studies have shown that URR or Kt/V give the best idea of your health on dialysis.

WHAT CAN I DO TO HELP KEEP MY *NUMBER* UP?

- Always go to all your scheduled dialysis sessions.
- Stay for the full session.
- Make sure you eat right.
- Follow the advice of your dialysis staff on how to stay healthy.
- Talk to your doctor if your *number* is low.
- Talk to the dialysis nurse if you need help with transportation, meals, or other things.

On the back of this pamphlet are two charts you can use to track your test result *number*.