The Johns Hopkins University
School of Medicine

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FAX COVER SHEET

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DETERMINED TO BE AN ADMINISTRATIVE

MARKING INITIALS: KBH DATE: 6/23/22
2022-0433-S

DATE: 10/15

TIME: 6:15 pm

TO: Dr. Arnie Epstein
Mr. IRA Magaziner

FAX#:

FROM: Michael E. Johns, M.D.

 # OF PAGES (including cover sheet): 4

Originals (____ will ✓ will not) be sent by mail or courier.

COVER MESSAGE:

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Baltimore, Maryland 21205-2196

JOHNS HOPKINS
UNIVERSITY

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Michael M.E. Johns, M.D.
Dean of the Medical Faculty
Vice President for Medicine

October 15, 1993

To: Dr. Arnie Epstein

From: Michael E. Johns, M.D.

Re: Proposal for Quality Management and Improvement

I have received the section on Quality Management and Improvement and have forwarded it to the rest of our work group for their comments. Enclosed for your review is a collation of a first set of responses from several members of the group. I hope they are helpful.

I must say that even though we have yet to hear from everyone in our group, there is a palpable sense of disappointment with the Quality Management and Improvement section. In general we feel that it is difficult to find evidence of consideration of the work and perspective that we have provided over the last few weeks.

We left our last meeting with Mr. Magaziner with the understanding that there was genuine interest in working with the concept that the academic health center would play a significant role in assuring quality in health professional education, outcomes research, and several other areas. We find instead that we have been relegated to the role of a minor player in regional consortia which "may" (or presumably may not) form to advise the NQMC. And this advisory role doesn't seem to correspond to the delineated functions, which are limited to "disseminating information," developing "continuing education" programs, and contracting with data management organizations for "consumer surveys."

There is the further implication that AHCs would stand to have some of their existing roles in education subsumed within regional non-profit foundations and/or regional health alliances. And in the entire eleven page document there appears to be only this single reference to any role for our national centers of health education and health services research.

MEJ/JFS
JHUSOM
10/15/93

Despite our disappointment we are going to try to continue to offer constructive suggestions for strengthening the proposal. We hope and expect that both this and other sections of the final proposal will more fully incorporate the vital resources and capabilities of our academic health centers.

I would be happy to talk to you about any of this over the weekend. My home number is 410/532-2904; my home fax is 410/435-6421. More feedback will follow on Monday. Thanks.

cc: Ira Magaziner, work group

MEJ/JPS
JHUSOM
10/15/93

Preliminary Suggestions for Revising Section on Quality Management and Improvement

1. In section on NQMC:

   - Give AHCs direct function by having NQMC consult with AHCs to develop new initiatives to improve quality performance of health professionals.

2. In section on Regional Quality Consortia:

   - Charge AHCs with developing health outcome reasearch for use in developing and refining continuing medical education.

3. In Consumer Education Programs:

   - Challenge AHCs to develop innovative patient education systems that would involve patients to a greater extent in making health care decisions.

4. In general:

   - The proposal appears to create an enormous new multi-layered bureaucracy where many tasks will overlap.

5. In general:

   - The academic health centers (AHCs) should play a central role in the National Quality Management Program (NQMP). This includes: participation of AHC leaders in the NQMP Council; developing information for quality management; providing technical assistance to alliances and health plans in quality management; disseminating information, including practice guidelines, that are part of the quality management program; developing a system of continuing professional education; and evaluating new technology and new procedures before they are introduced widely into the medical care system. The Act makes available adequate financial support for clinical research (including outcomes research) to allow AHCs to carry out these quality management functions.

- Sustaining the "training and education" provision of the plan's core public health functions section that calls for the "training with special emphasis on public health professionals such as epidemiologists, biostatisticians, health educators, public health administrators," among others.

- Include the education and training of public health professionals in the section on innovative strategies for addressing priority health needs of regional and national significance: the shortage of public health professionals is serious (HHS/PHS report to Congress, 1991).

- National data collection and analysis efforts must be expanded concerning issues related to the public health workforce. There is a need to develop centralized linkage at federal, state and local levels to collect uniform data; e.g., workforce numbers, educational levels, public health educational needs, etc.

- There is a need to provide structured short-term academic training for the existing public health workforce. This process should be viewed as a continuum throughout the career of a public health professionals.

- Two percent (2%) of national health care expenditures should be set aside to support the core functions of public health including the education of the public health workforce and health professionals to accomplish these core functions.

- Consolidation of current federal academic public health supports programs into a new authorization that would earmark $50 million to train future public health professionals (a **Public Health Service Corps**) to usher in health care reform at the federal, state and local level. Under this plan, schools of public health and accredited programs in preventive medicine, would train and educate a cadre of new public health professionals, with specials skills and competencies needed to function in a managed competition environment, for careers in official public health agencies and alliances.

- Greater emphasis of coordination of federal, state, and local environmental health programs and services including increased attention to the training and education of environmental health specialists such as toxicologists, environmental epidemiologists, hazard communication specialists, among others.

- Sustaining inclusion of clinical preventive services in the benefits package (with no co-payments or deductibles).

In summary, expertise to provide public health services makes increased education of the existing and future public health workforce in such disciplines as organizational expertise, cultural sensitivity, interdisciplinary cooperation, biostatistics and epidemiology, planning and program evaluation, and financial management, to name a few, critical to the success of health care reform effort.

# # #

JCM

JCM

FACSIMILE COVER LETTER

DATE: October 18, 1993

TO: Ira Magaziner/Arnie Epstein
THE WHITE HOUSE

FROM: John E. Wennberg, MD, MPH
Director
The Center for the Evaluative Clinical Sciences
Dartmouth Medical School
7251 Strasenburgh
Hanover, NH 03755-3863

FAX Phone: (603) 650-1225
Voice Phone: (603) 650-1684

Number of Pages Including Cover Letter: 11

MESSAGE: I've put in bold the suggested changes in the Quality Management Section.

QUALITY MANAGEMENT AND IMPROVEMENT
SUMMARY

Many Americans worry that strong action to restrain costs will compromise the quality of health care. The goal of the Health Security Act is to improve health care by building attention to quality into all levels. To that end, a national quality management program transforms the current prescriptive approach to quality into a system focused on performance measures and continuous improvement.

Traditional quality assurance depends on after-the-fact checkers relying primarily on external reviews, forms and process checks to ensure that treatment occurred as it should. Insurance companies, peer review organizations, state and federal regulatory agencies audit the work of hospitals, offices, clinics and laboratories, searching for infractions and punishing rule breakers. Physicians and other providers, hospitals and insurers create special departments and hire personnel devoted to the demands of quality checkers; their job is to make the right forms appear in the right files and that checklists are checked correctly.

Patients play a minor role in the system of micro-management, lacking reliable information upon which to compare treatment options or the quality of health plans and providers. Yet rational choice among treatments depends on shared decisionmaking between physician and patient.

Patient-focused continuous improvement, in contrast, depends on improving the outcomes of care and assuring that patient needs and preferences are met. The Health Security Act provides the professions with the resources they need to accept responsibility for improving quality in the Nation's health care system. A sophisticated data system provides the needed performance measures. Based largely on routinely collected data, these measures deliver to consumers and patients useful information to make informed choice possible. Three components form the nexus of the quality improvement program:

- The health care information system, which provides the basic elements through which consumers learn about the quality of their care.
- The program to simplify administration, which frees providers to focus more attention on quality.
- Active efforts at regional and alliance levels to support quality improvement.

Each component plays an equally critical role; no one is more vital than the others. The quality management program represents a seamless approach to bringing about improvement.

NATIONAL QUALITY MANAGEMENT PROGRAM: PROGRAM SPECIFICATIONS

Under the Health Security Act, the responsibility for quality rests with a National Quality Management Council, regional quality foundations, states, alliances, health plans and providers.

A one percent per capita levy on insurance premiums flows through regional health alliances to fund the program.

NATIONAL ROLE

A National Quality Management Council under the National Health Board, consists of 15 members representative of the population. Appointed by the President, it includes representatives of consumer groups, health plans, states, purchasers of care and experts in public health and quality of care.

The National Quality Management Council:

- Develops the core set of quality and performance measures and consumer survey questions and updates them over time to reflect changing goals for quality improvement in health care.

  As part of that effort, the program develops sampling strategies to ensure that performance reports include populations difficult to reach, including consumers who fail to enroll in a health plan or resign from plans.

- Sets national goals for performance on selected quality measures.

- Establishes minimal standards of access and quality for plans on selected measures.

- **Review and approve plans for operation developed by the Regional Professional Foundation. In developing their plans, each Foundation is asked to specify how their organization will assure that the following criteria for quality are met:**

  * **Knowledge about relevant treatment options are freely communicated to patients,**
  * **The choice among effective treatment options is based on the preferences of patients,**
  * **The process and outcomes of care are continuously evaluated and improved.**

- Supports research, technology assessment and development of reliable tools for measuring health outcomes.

- Evaluates the impact of health reform on the quality of care.

- Reports annually on performance of the health care system.

- Reviews and recommends changes to the quality measures annually and establishes a five-year priority list for measures to be included in the future.

- Uses the national network of regional centers to obtain quality management data. (See section on Information Systems and Administrative Simplification.)

ROLE OF REGIONAL QUALITY FOUNDATIONS:

Representatives of academic health centers, schools of publish health, health professional schools (including, but not limited to, medical schools), **practicing physicians**, health plans and alliances will form private, non-profit regional consortia. Representatives from these regional consortia will advise the National Quality Management Council.

The Regional Professional Foundations will be organized over an eighteen month period to perform the following functions:

- **Develop and maintain regional networks among health care providers to evaluate practice variations, improve the quality of care, conduct research into the outcomes of care and assure that patients are informed about treatment options and choice reflects patient preferences.**

- **Develop programs in lifetime learning for the region's workforce to assure that the professions remain abreast of new knowledge, acquire new skills and adopt new roles as technology and societal demands change.**

- **Perform other technical assistance and infra-structure building tasks as the health alliance may contract with the Foundation to perform. These could include (but are not limited to) evaluating the need for professional manpower in local and regional markets; building infra-structure in underserved geographic areas or**

undercapitalized areas such as primary care and community based care.

- **Contract with one or more organizations linked to the national data network.**

- **Contract for the administration of consumer surveys that measure access to care, use of health services, outcomes and satisfaction and document shared decisionmaking.**

Planning grants would go to an eligible not-for-profit entity such as an existing Professional Foundation, a medical school, medical society or state agency. The geographic base for the Foundation will include (1) the natural referral area of academic medical centers as empirically defined by patient origin studies; (2) a population of sufficient size to study and reduce unwanted variations in the processes and outcomes for major operations such as bypass surgery.

STATE ROLE

As part of the quality management program, states assume responsibility to:

- Develop and implement plans to meet enrollment, access and quality standards established by the federal government.

- Assure that plans and providers meet essential national standards through licensure and certification procedures.

- Monitor the extent to which plans make the full range of benefits covered in the guaranteed package accessible to all population groups.

- Prepare statewide comparative reports on the performance of alliances.

- Establish in each alliance a premium check-off system through which up to $1 per participant can be allocated for support of a consumer advocacy program.

ROLE OF ALLIANCES

As part of the quality management program, health alliances:

- Resolve consumer complaints, grievances and requests to leave a health plan.

- Disseminate information related to quality of health plans, providers and practitioners and assure through

their negotiations with plans that performance and quality standards are met.

- Conduct consumer education programs.
- Provide technical assistance.
  - Organizations eligible to undertake this role include public-private partnerships, consortia led by academic medical centers, and others.
  - Technical assistance may include activities such as: fostering collaboration among health plans and providers; disseminating information about successful quality-improvement programs, disseminating practice guidelines and research findings; and providing educational courses and other forums for providers. Encourages the adoption of employee participation committees and other quality programs.
  - Technical assistance targets improving quality management practices. It is not designed to regulate or interfere with the administration of plans and providers.
  - Providers and health plans are not required to use technical assistance, although health plans are accountable for improving performance on national quality measures.

ROLE OF HEALTH PLANS

As part of the quality management programs, health plans:

- Measure and disclose performance on quality measures.
- Report on, maintain and improve the quality of care delivered by providers and practitioners.
- Meet national, uniform conditions of participation established by the National Health Board (See "Health Plans").

PERFORMANCE REPORTS

Annual performance reports for each health plan create a public system of accountability for quality and provide consumers with useful comparative information.

Performance report include information on the performance of alliances and health plans on as many as 50 measures of access to care, appropriateness of care, health outcomes, health promotion,

disease prevention, satisfaction with care **and success in promoting shared decisionmaking.**

The reports provide the results of a smaller number of quality measures for health care institutions, doctors and other practitioners if the available information is statistically meaningful. State performance reports include trends, results of national quality measures and of goals for national performance on access, appropriateness and health outcomes.

The following criteria determine the selection of national measures of quality performance:

- The measures reflect important aspects of care in terms of prevalence of illness, morbidity, mortality or cost.
- The set is representative of the range of services provided to consumers by the entities in question.
- Measures are reliable and valid and data needed for calculation can be obtained without undue burden.
- Performance on measures included in the set vary widely among the entities on the performance report.
- When the measures are outcomes of care, performance lies within the control of providers and adequate risk adjustment can be accomplished.
- The measures incorporate minimal standard for meeting public health objectives.

DEVELOPING INFORMATION FOR QUALITY MANAGEMENT

Health plans, providers and alliances report information required for the national quality management program through an electronic network linked nationally. The electronic networks have a contractual relationship with the regional quality consortia. Information required includes data related to enrollment, clinical encounters, consumer satisfaction and specific quality measures.

These centers electronically link regional quality programs, health alliances and plans, providing quality and utilization information for each health plan and provider as well as comparative information on other health plans and states.

To supplement routinely collected information, health plans gather clinical data specified by the national quality management

program from samples of medical records. Results from consumer surveys , in combination with other information, gauge access to health care, use of service, outcomes and satisfaction.

THE KNOWLEDGE BASE TO IMPROVE THE QUALITY OF CARE

To promulgate information about best practices and effective treatment approaches, the National Quality Management Program:

- Develops the survey instrument; states may add quality measures of local interest.
- Develops clinical practice guidelines, methodology standards, and an evaluation and voluntary certification process developed by the private sector.
- Operates a clearinghouse and dissemination program for practice guidelines.
- Disseminates information documenting clinically ineffective procedures and treatments.
- Supports research on topics central to quality management and improvement, including outcomes research, dissemination methods, ways of measuring quality and design of electronic information systems and new ways of organizing work systems.
- Establishes scientific standards and procedures for evaluating the clinical appropriateness of protocols used to manage health service utilization.
- Defines priorities for health-care evaluation research and recommends projects. The priorities target diagnoses associated with the highest levels of uncertainty in treatment decisions, widest variation in practice patterns, significant costs and incidence.

The Regional Professional Foundations:

- **Undertakes program to investigate the processes of care to identify and reduce sources of variation in mortality and other untoward outcomes.**
- **Participates in outcomes research in cooperation with PORTs and other research projects under the national outcomes research agenda.**
- **Develops and validates practice guidelines in concert with the national quality management board.**
- Contract with survey firms to conduct statistically valid surveys of sample populations to gather information related to consumer satisfaction, access to

care and health outcomes. Survey samples include over-sampling of populations considered to be at risk for inadequate health care.

- Disseminates practice guidelines that assist providers in achieving quality standards and underpin national measures of quality.

STREAMLINING REGULATORY ACTIVITIES

Minimum standards for health care institutions. the national quality management programs develops uniform standards for licensing of health care institutions that focus on essential performance requirements related to patient care. As they are developed, those standards replace current regulations except in areas of fire safety, sanitation and patient rights and without undermining recent reforms in nursing home care.

When the new standards are in place, agencies charged with certifying health institutions focus their attention on institutions with problematic records, responding to complaints and randomly selected validation sites.

By January 1, 1996, the National Quality Management Program completes demonstration projects for new performance standards and revises standards according to the findings. Demonstration projects evaluate the impact of these standards in assuring quality of care, reducing cost and burdens on providers.

Current standards are retained until new ones are tested, promulgated, evaluated and implemented. In the interim, government agencies responsible for licensing and certifying health care institutions coordinate inspections, reduce paperwork and control the number of inspections.

Medicare Peer Review Organizations. The peer review organization system under Medicare continues until the new quality system is implemented and the Secretary of the Department of Health and Human Services determines that Medicare enrollees are protected adequately though National Quality Management Program. PROs end at that time.

During the interim, the PRO program is streamlined. (See Administrative Simplification)

The Clinical Laboratory Improvement Act. Regulation of clinical laboratory testing refocuses to emphasize quality protection while reducing administrative burdens.

Regulation continues for labs that:

a) Perform a comprehensive menu of tests; or

b) Perform a large volume of tests (50,000 or

greater); or

c) Engage in critical testing (a test is critical if an answer is needed quickly or an error can result in serious harm to an individual); or

d) Conduct testing to monitor care while it is being delivered.

- Ease regulatory burdens on laboratories performing simple tests.

  Exempt laboratories performing waived and microscopy from all requirements under CLIA, including registration and payment of fees to the Department of Health and Human Services. Approximately 79,000 labs.

  Add more simple tests to the list of waivered tests.

  In accordance with recommendations by the Clinical Laboratory Improvement Advisory Committee (CLIAC), the physician-performed microscopy category are expanded to include tests performed by midlevel health care providers (e.g., nurse practitioners, physician's assistants, nurse midwives, etc.).

- Ease regulatory burden on laboratories performing moderately complexity tests.

  Create a new category of moderately complex tests performed using FDA-approved equipment subject to less stringent inspection requirements.

  By January 1, 1996, the Secretary of the Department of Health and Human Services issues a report on the extent to which regulation of laboratories performing moderately complex tests should continue. Within six months, the Secretary determines, based on the report, the need for cost regulation for these laboratories.

- Revise personnel standards to relieve in urban and rural areas.

  In accordance with recommendations by the CLIAC, individuals currently engaged in laboratory testing or supervision may continue to perform such testing in the absence of evidence of demonstrated poor performance.

  To address the concerns of rural and underserved areas, the Department of Health and Human Service modify personnel requirements for certain laboratory positions.

- Focus proficiency testing primarily on education.

Department of Health and Human Services only takes proficiency-related enforcement actions if a laboratory's performance is extremely poor or it has failed to take corrective action after proficiency problems are identified.

Department of Health and Human Services work with congressional committees to develop a modified approach to cytology proficiency testing.

- Streamline inspections.

  Department of Health and Human Services targets on-site inspections at high-volume, high-risk labs. Inspections are announced.

- Expand information and education activities.

  To eliminate confusion and misinformation about CLIA requirements, the Department of Health and Human Services works with professional groups to provide information and education.

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The Department has three major concerns with the plan as reviewed on October 18.

1. The conditions of participation for plans are now poorly defined and State responsibility for certifying plans does not have a clear basis in the law. The Department believes that the NQMC should develop conditions of participation for plans and that the States should have responsibility for certifying that the plans meet these conditions.

2. The provision of technical assistance for quality improvement is diffused, bureaucracies have been multiplied, and funding is not assured. The Department believes that States should have responsibility for securing technical assistance through contracts for which consortia and others would compete. Funding should be guaranteed from premiums at a level to be set by the National Health Board.

3. Responsibilities for the survey, research, and guidelines functions should be redefined.

-- Surveys must be nationally uniform. Section 5004 clearly and properly assigns this responsibility to NQMC, but Section 5009 suggests that the surveys might be carried out by multiple entities. Results would not be uniform or comparable. The Department believe that the capability to carry out the surveys already exists in the Department and that a parallel capability in NQMC staff would be redundant and counterproductive.

-- NQMC should specify needs in areas of research and guidelines, but these should be carried out by PHS. NQMC will have insufficient staff, and creating the staff would also create parallel and overlapping bureaucracies.

In addition, the Department has identified two areas that will create problems of perception relating to section 5008 (licensing). First, the date for completion of demonstrations, January 1, 1996, is blatantly unrealistic because the proposed standards to be demonstrated are most unlikely to have been completed by that time; a more realistic date is 3 years after enactment. Second, nursing home regulations should be explicitly excluded or given a much later date; advocates of nursing home reform have indicated that including nursing homes in this process will be perceived as a betrayal.

THE AMERICAN SECURITY ACT OF 1993

Draft Bill Review

[redacted] Reviewer's Name: _____ Tel: _____

Date of Review: _____ Time: _____

Version (Dates) of Draft Bill Being Reviewed: _____

* * * * * * * * * * * * * * * * *

Sections of Draft Bill Reviewed: _____

_____

Reviewed in light of the Draft Health Plan (9/7/93) pp. _____

Drafting Clarifications:

J.E-17 line 3 Obligation

Section 1203 State certification
Reservation
Mandatory Benefits

To Ira Magaziner
Lynn Margherio

From Risa Lavizzo-Mourey
Arnie Epstein

Attached is a revised version of the Quality Management Program: Program specifications. The revisions incorporate (to the extent possible) the suggestions made by Jack Wennberg and the Deans.

This memo describes the changes and the rationale for not incorporating some of the requested changes. Please review these changes and edit if necessary. We are prepared to make the necessary changes to the legislative language as soon as Ira signs off. Both of us are traveling on Monday, but can work while in transit or on Monday night so as to have the job finished by Tuesday.

All of the changes refer to the National Role and the Regional Foundations. The changes are as follows:

1. The name of the regional consortia was changed to Regional Professional Foundations and their formantion was mandated, as suggested by Jack Wennberg and the Deans.

2. The suggested composition for the Regional Professional Foundations was modified. However, we did not mandate inclusion of any particular discipline or professional school. Rather we described very broadly based organizations. We believe that they will need to include most of the organizations described if the Foundations are to accomplish the functions described, but do not want to be prescriptive. The deans would have them more narrowly defined and would mandate that AHC's have the lead, but we believe this would be inconsistent with the spirit of the reform and ignores the fact that in some regions the AHCs are not the experts in quality improvement.

3. The Regional Foundations will be reviewed and awarded by the National Board.

4. The Foundations were given some additional functions - to provide technical assistance related to building infrastructure including the study of practice variation and to develop and validate clinical practice guidelines. We did not mandate that the Foundations conduct outcomes research, as suggested by Wennberg, because this function is not essential to the other regional quality improvement functions. The research conducted by these foundations could be synergistic with the regional quality improvement activities and is a way to accomplish national health services research priorities. Therefore, we highlighted that the Foundations could apply for funds to conduct health services research.

5. We did not incorporate Jack Wennberg's suggestion to make "success in promoting shared decision making" a categrory of measures in the report card, because it does not yet have the same universal credibility that the other categories have. Rather we highlighted this as an area for future research.

Risa can be reached at 215 843-9875 on Sunday and until 9 am on Monday. After 9 am call Pat at 301 594-6662 and she can get a message to me in New Jorsy. Arnie can be reached at the usual numbers.

QUALITY MANAGEMENT AND IMPROVEMENT

SUMMARY

Many Americans worry that strong action to restrain costs will compromise the quality of health care. The goal of the Health Security Act is to improve health care by building attention to quality into all levels. To that end, a national quality management program transforms the current prescriptive approach to quality into a system focused on performance measures and continuous improvement.

Traditional quality assurance depends on after-the-fact checkers relying primarily on external reviews, forms and process checks to ensure that treatment occurred as it should. Insurance companies, peer review organizations, state and federal regulatory agencies audit the work of hospitals, offices, clinics and laboratories, searching for infractions and punishing rule beakers. Physicians and other providers, hospitals and insurers create special departments and hire personnel devoted to the demands of quality checkers; their job is to make the right forms appear in the right files and that checklists are checked correctly.

Patients play a minor role in the system of micro-management, lacking reliable information upon which to compare treatment options or the quality of health plans and providers. Yet rational choice among treatments depends on shared decisionmaking between physician and patient.

Patient-focused continuous improvement, in contrast, depends on improving the outcomes of care and assuring that patient needs are met. The Health Security Act provides the professions with the resources they need to accept responsibility for improving quality in the Nations' health care system. A sophisticated data system provides the needed performance measures. Based largely on routinely collected data, these measures deliver to consumers and patients useful information to make informed choice possible. Three components form the nexus of the quality improvement program:

- The health care information system, which provides the basic elements through which consumers learn about the quality of their care.
- The program to simplify administration, which frees providers to focus more attention on quality.
- Active efforts at regional and alliance levels to

support quality improvement.

Each component plays an equally critical role; no one is more vital than the others. The quality management program represents a seamless approach to bringing about improvement.

NATIONAL QUALITY MANAGEMENT PROGRAM: PROGRAM SPECIFICATIONS

Under the Health Security Act, the responsibility for quality rests with a National Quality Management Council, regional quality foundations, states, alliances, health plans and providers.

A one percent per capita levy on insurance premiums flows through regional health alliances to fund the program. ~~[IRA -- WHAT ABOUT THE CORPORATE ASSESSMENT? IS THIS IN ADDITION TO THE $3.5B GOING TO THE AHC POOL FROM THE PREMIUM ASSESSMENT?]~~

NATIONAL ROLE

A National Quality Management Council under the National Health Board, consists of 15 members representative of the population. Appointed by the President, it includes representatives of consumer groups, health plans, states, purchasers of care and experts in public health and quality of care.

The National Quality Management Council:

- Develops the core set of quality and performance measures and consumer survey questions and updates them over time to reflect changing goals for quality improvement in health care.

  As part of that effort, the program develops sampling strategies to ensure that performance reports include populations difficult to reach, including consumers who fail to enroll in a health plan or resign from plans.

- Sets national goals for performance on selected quality measures.

- Establishes minimal standards of access and quality for plans on selected measures.

- Supports research, technology assessment and development of reliable tools for measuring health outcomes.

- Evaluates the impact of health reform on the quality of care.

- Reports annually on performance of the health care system.

- Reviews and recommends changes to the quality measures annually and establishes a five-year priority list for measures to be included in the future.

- Approves and funds Regional Professional Foundations based on technical merit and the ability of these foundations to meet needs of regional alliances in participating states.

- Uses the national network of regional centers to obtain quality management data. (See section on Information Systems and Administrative Simplification.)

ROLE OF REGIONAL PROFESSIONAL FOUNDATIONS:

Regional Professional Foundations will be formed as private, non-private regional consortia. Included in the foundations may be academic health centers as well as schools of public health, health professional schools (including, but not limited to, medical schools, nursing schools, dental schools and allied health schools), health plans, alliances and practicing physicians. Representatives from these regional foundations will advise the National Quality Management Council

The regional professional foundations perform the following functions:

- Expand and disseminate information about best clinical practices, including development and validation of clinical practice guidelines and innovative uses of the health care workforce.

- Develop programs in lifetime learning for the region's workforce to assure that the professions remain abreast of new knowledge, acquire new sills and adopt new roles as technology and societal demands change.

- Perform technical assistance related to building the infra-structure of the region. This could include (but is not limited to) evaluating the need for professional manpower in local and regional markets; evaluating local variations in care; and building infra-structure in underserved geographical areas or undercapitalized areas such as primary care and community based care.

- Contract with one or more organizations linked to the national data network.

- Contract for the administration of consumer surveys that measure access to care, use of health services, outcomes and satisfaction.

The regional foundations may contract with alliances to provide technical assistance and may apply for grants to carry out health services research as described in that section of this document.

STATE ROLE

As part of the quality management program, states assume responsibility to:

- Develop and implement plans to meet enrollment, access and quality standards established by the federal government.

- Assure that plans and providers meet essential national standards through licensure and certification procedures.

- Monitor the extent to which plans make the full range of benefits covered in the guaranteed package accessible to all population groups.

- Prepare statewide comparative reports on the performance of alliances.(**Ira -IS THIS LESS DETAILED REPORT OK OR DO YOU WANT IT OUT?)**

- Establish in each alliance a premium check-off system through which up to $1 per participant can be allocated for support of a consumer advocacy program.

ROLE OF ALLIANCES

As part of the quality management program, health alliances:

- Resolve consumer complaints, grievances and requests to leave a health plan.

- Disseminate information related to quality and access to consumers.

- Prepare comparative reports on the quality of health plans, providers and practitioners and assure through their negotiations with plans that performance and quality standards are met.

- Conduct consumer education programs.

- Provide technical assistance.

  - Organizations elible to undertake this role include public-private partnerships, regional professional foundations, academic medical centers, or others.

  - Technical assistance may include activities such as: fostering collaboration among health plans and providers; disseminating information about successful quality-improvement programs, disseminating practice guidelines and research

findings; and providing educational courses and other forums for providers. Encourages the adoption of employee participation committees and other quality programs.

- Technical assistance targets improving quality management practices. It is not designed to regulate or interfere with the administration of plans and providers.

- Providers and health plans are not required to use technical assistance, although health plans are accountable for improving performance on national quality measures.

ROLE OF HEALTH PLANS

As part of the quality management program, health plans:

- Measure and disclose performance on quality measures.

- Report on, maintain and improve the quality of care delivered by providers and practitioners.

- Meet national, uniform conditions of participation established by the National Health Board (See "Health Plans").

PERFORMANCE REPORTS

Annual performance reports for each health plan create a public system of accountability for quality and provide consumers with useful comparative information.

Performance report include information on the performance of alliances and health plans on as many as 50 measures of access to care, appropriateness of care, health outcomes, health promotion, disease prevention and satisfaction with care.

The reports provide the results of a smaller number of quality measures for health care institutions, doctors and other practitioners if the available information is statistically meaningful. State performance reports include trends, results of national quality measures and of goals for national performance on access, appropriateness and health outcomes.

The following criteria determine the selection of national measures of quality performance:

- The measures reflect important aspects of care in terms of prevalence of illness, morbidity, mortality or cost.
- The set is representative of the range of services provided to consumers by the entities in question.
- Measures are reliable and valid and data needed for calculation can be obtained without undue burden.
- Performance on measures included in the set vary widely among the entities on the performance report.
- When the measures are rates of process of care, these processes are linked by strong scientific evidence to health outcomes.
- When the measures are outcomes of care, performance lies within the control of providers and adequate risk adjustment can be accomplished.
- The measures incorporate minimal standard for meeting public health objectives.

DEVELOPING INFORMATION FOR QUALITY MANAGEMENT

Health plans, providers and alliances report information required for the national quality management program through an electronic network linked nationally. The electronic networks have a contractual relationship with the regional quality consortia. Information required includes data related to enrollment, clinical encounters, consumer satisfaction and specific quality measures.

These centers electronically link regional quality programs, health alliances and plans, providing quality and utilization information for each health plan and provider as well as comparative information on other health plans and states.

To supplement routinely collected information, health plans gather clinical data specified by the national quality management program from samples of medical records. Results from consumer surveys, in combination with other information, gauge access to health care, use of service, outcomes and satisfaction.

THE KNOWLEDGE BASE TO IMPROVE THE QUALITY OF CARE

To promulgate information about best practices and effective treatment approaches, the National Quality Management Program:

- Develops the survey instrument; states may add quality measures of local interest.
- Develops clinical practice guidelines, methodology standards, and an evaluation and voluntary certification process developed by the private sector.
- Operates a clearinghouse and dissemination program for practice guidelines.
- Disseminates information documenting clinically ineffective procedures and treatments.
- Supports research on topics central to quality management and improvement, including outcomes research, dissemination methods, ways of measuring quality and shared decision making, and design of electronic information systems and new ways of organizing work systems.
- Establishes scientific standards and procedures for evaluating the clinical appropriateness of protocols used to manage health service utilization.

- Defines priorities for health-care evaluation research and recommends projects. The priorities target diagnoses associated with the highest levels of uncertainty in treatment decisions, widest variation in practice patterns, significant costs and incidence.

The regional professional foundations:

- Contract with survey firms to conduct statistically valid surveys of sample populations to gather information related to consumer satisfaction, access to care and health outcomes. Survey samples include over-sampling of populations considered to be at risk for inadequate health care.

- Disseminate practice guidelines that assist providers in achieving quality standards and underpin national measures of quality.

STREAMLINING REGULATORY ACTIVITIES

Minimum Standards for Health Care Institutions. The National Quality Management Programs develops uniform standards for licensing of health care institutions that focus on essential performance requirements related to patient care. As they are developed, those standards replace current regulations except in areas of fire safety, sanitation and patient rights and without undermining recent reforms in nursing home care.

When the new standards are in place, agencies charged with certifying health institutions focus their attention on institutions with problematic records, responding to complaints and randomly selected validation sites.

The Johns Hopkins University
School of Medicine

~~CONFIDENTIAL~~

FAX COVER SHEET

Michael M.E. Johns, M.D.
Dean of the Medical Faculty
Vice President for Medicine
FAX#: (410) 955-0889
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DETERMINED TO BE AN ADMINISTRATIVE

MARKING INITIALS: KBH DATE: 6/23/22
2022-04333

DATE: 10/15

TIME: 6:15 pm

TO: Dr. Arnie Epstein
Mr. IRA Magaziner

FAX#:

FROM: Michael E. Johns, M.D.

 # OF PAGES (including cover sheet): 4

Originals (____ will _✓_ will not) be sent by mail or courier.

COVER MESSAGE:

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JOHNS HOPKINS
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Michael M.E. Johns, M.D.
Dean of the Medical Faculty
Vice President for Medicine

October 15, 1993

To: Dr. Arnie Epstein

From: Michael E. Johns, M.D.

Re: Proposal for Quality Management and Improvement

I have received the section on Quality Management and Improvement and have forwarded it to the rest of our work group for their comments. Enclosed for your review is a collation of a first set of responses from several members of the group. I hope they are helpful.

I must say that even though we have yet to hear from everyone in our group, there is a palpable sense of disappointment with the Quality Management and Improvement section. In general we feel that it is difficult to find evidence of consideration of the work and perspective that we have provided over the last few weeks.

We left our last meeting with Mr. Magaziner with the understanding that there was genuine interest in working with the concept that the academic health center would play a significant role in assuring quality in health professional education, outcomes research, and several other areas. We find instead that we have been relegated to the role of a minor player in regional consortia which "may" (or presumably may not) form to advise the NQMC. And this advisory role doesn't seem to correspond to the delineated functions, which are limited to "disseminating information," developing "continuing education" programs, and contracting with data management organizations for "consumer surveys."

There is the further implication that AHCs would stand to have some of their existing roles in education subsumed within regional non-profit foundations and/or regional health alliances. And in the entire eleven page document there appears to be only this single reference to any role for our national centers of health education and health services research.

MEJ/JFS
JHUSOM
10/15/93

Despite our disappointment we are going to try to continue to offer constructive suggestions for strengthening the proposal. We hope and expect that both this and other sections of the final proposal will more fully incorporate the vital resources and capabilities of our academic health centers.

I would be happy to talk to you about any of this over the weekend. My home number is 410/532-2904; my home fax is 410/435-6421. More feedback will follow on Monday. Thanks.

cc: Ira Magaziner, work group

MEJ/JPS
JHUSOM
10/15/93

Preliminary Suggestions for Revising Section on Quality Management and Improvement

1. In section on NQMC:

   - Give AHCs direct function by having NQMC consult with AHCs to develop new initiatives to improve quality performance of health professionals.

2. In section on Regional Quality Consortia:

   - Charge AHCs with developing health outcome reasearch for use in developing and refining continuing medical education.

3. In Consumer Education Programs:

   - Challenge AHCs to develop innovative patient education systems that would involve patients to a greater extent in making health care decisions.

4. In general:

   - The proposal appears to create an enormous new multi-layered bureaucracy where many tasks will overlap.

5. In general:

   - The academic health centers (AHCs) should play a central role in the National Quality Management Program (NQMP). This includes: participation of AHC leaders in the NQMP Council; developing information for quality management; providing technical assistance to alliances and health plans in quality management; disseminating information, including practice guidelines, that are part of the quality management program; developing a system of continuing professional education; and evaluating new technology and new procedures before they are introduced widely into the medical care system. The Act makes available adequate financial support for clinical research (including outcomes research) to allow AHCs to carry out these quality management functions.

MEJ/JPS
JHUSOM
10/15/93

- Sustaining the "training and education" provision of the plan's core public health functions section that calls for the "training with special emphasis on public health professionals such as epidemiologists, biostatisticians, health educators, public health administrators," among others.

- Include the education and training of public health professionals in the section on innovative strategies for addressing priority health needs of regional and national significance: the shortage of public health professionals is serious (HHS/PHS report to Congress, 1991).

- National data collection and analysis efforts must be expanded concerning issues related to the public health workforce. There is a need to develop centralized linkage at federal, state and local levels to collect uniform data; e.g., workforce numbers, educational levels, public health educational needs, etc.

- There is a need to provide structured short-term academic training for the existing public health workforce. This process should be viewed as a continuum throughout the career of a public health professionals.

- Two percent (2%) of national health care expenditures should be set aside to support the core functions of public health including the education of the public health workforce and health professionals to accomplish these core functions.

- Consolidation of current federal academic public health supports programs into a new authorization that would earmark $50 million to train future public health professionals (a **Public Health Service Corps**) to usher in health care reform at the federal, state and local level. Under this plan, schools of public health and accredited programs in preventive medicine, would train and educate a cadre of new public health professionals, with specials skills and competencies needed to function in a managed competition environment, for careers in official public health agencies and alliances.

- Greater emphasis of coordination of federal, state, and local environmental health programs and services including increased attention to the training and education of environmental health specialists such as toxicologists, environmental epidemiologists, hazard communication specialists, among others.

- Sustaining inclusion of clinical preventive services in the benefits package (with no co-payments or deductibles).

In summary, expertise to provide public health services makes increased education of the existing and future public health workforce in such disciplines as organizational expertise, cultural sensitivity, interdisciplinary cooperation, biostatistics and epidemiology, planning and program evaluation, and financial management, to name a few, critical to the success of health care reform effort.

# # #

JCM

JCM

FACSIMILE COVER LETTER

DATE: October 18, 1993

TO: Ira Magaziner/Arnie Epstein
THE WHITE HOUSE

FROM: John E. Wennberg, MD, MPH
Director
The Center for the Evaluative Clinical Sciences
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Number of Pages Including Cover Letter: 11

MESSAGE: I've put in bold the suggested changes in the Quality Management Section.

QUALITY MANAGEMENT AND IMPROVEMENT
SUMMARY

Many Americans worry that strong action to restrain costs will compromise the quality of health care. The goal of the Health Security Act is to improve health care by building attention to quality into all levels. To that end, a national quality management program transforms the current prescriptive approach to quality into a system focused on performance measures and continuous improvement.

Traditional quality assurance depends on after-the-fact checkers relying primarily on external reviews, forms and process checks to ensure that treatment occurred as it should. Insurance companies, peer review organizations, state and federal regulatory agencies audit the work of hospitals, offices, clinics and laboratories, searching for infractions and punishing rule breakers. Physicians and other providers, hospitals and insurers create special departments and hire personnel devoted to the demands of quality checkers; their job is to make the right forms appear in the right files and that checklists are checked correctly.

Patients play a minor role in the system of micro-management, lacking reliable information upon which to compare treatment options or the quality of health plans and providers. Yet rational choice among treatments depends on shared decisionmaking between physician and patient.

Patient-focused continuous improvement, in contrast, depends on improving the outcomes of care and assuring that patient needs and preferences are met. The Health Security Act provides the professions with the resources they need to accept responsibility for improving quality in the Nation's health care system. A sophisticated data system provides the needed performance measures. Based largely on routinely collected data, these measures deliver to consumers and patients useful information to make informed choice possible. Three components form the nexus of the quality improvement program:

- The health care information system, which provides the basic elements through which consumers learn about the quality of their care.
- The program to simplify administration, which frees providers to focus more attention on quality.
- Active efforts at regional and alliance levels to support quality improvement.

Each component plays an equally critical role; no one is more vital than the others. The quality management program represents a seamless approach to bringing about improvement.

NATIONAL QUALITY MANAGEMENT PROGRAM: PROGRAM SPECIFICATIONS

Under the Health Security Act, the responsibility for quality rests with a National Quality Management Council, regional quality foundations, states, alliances, health plans and providers.

A one percent per capita levy on insurance premiums flows through regional health alliances to fund the program.

NATIONAL ROLE

A National Quality Management Council under the National Health Board, consists of 15 members representative of the population. Appointed by the President, it includes representatives of consumer groups, health plans, states, purchasers of care and experts in public health and quality of care.

The National Quality Management Council:

- Develops the core set of quality and performance measures and consumer survey questions and updates them over time to reflect changing goals for quality improvement in health care.

  As part of that effort, the program develops sampling strategies to ensure that performance reports include populations difficult to reach, including consumers who fail to enroll in a health plan or resign from plans.

- Sets national goals for performance on selected quality measures.

- Establishes minimal standards of access and quality for plans on selected measures.

- **Review and approve plans for operation developed by the Regional Professional Foundation. In developing their plans, each Foundation is asked to specify how their organization will assure that the following criteria for quality are met:**

  * **Knowledge about relevant treatment options are freely communicated to patients,**
  * **The choice among effective treatment options is based on the preferences of patients,**
  * **The process and outcomes of care are continuously evaluated and improved.**

- Supports research, technology assessment and development of reliable tools for measuring health outcomes.

- Evaluates the impact of health reform on the quality of care.

- Reports annually on performance of the health care system.

- Reviews and recommends changes to the quality measures annually and establishes a five-year priority list for measures to be included in the future.

- Uses the national network of regional centers to obtain quality management data. (See section on Information Systems and Administrative Simplification.)

ROLE OF REGIONAL QUALITY FOUNDATIONS:

Representatives of academic health centers, schools of publish health, health professional schools (including, but not limited to, medical schools), **practicing physicians**, health plans and alliances will form private, non-profit regional consortia. Representatives from these regional consortia will advise the National Quality Management Council.

The Regional Professional Foundations will be organized over an eighteen month period to perform the following functions:

- **Develop and maintain regional networks among health care providers to evaluate practice variations, improve the quality of care, conduct research into the outcomes of care and assure that patients are informed about treatment options and choice reflects patient preferences.**

- **Develop programs in lifetime learning for the region's workforce to assure that the professions remain abreast of new knowledge, acquire new skills and adopt new roles as technology and societal demands change.**

- **Perform other technical assistance and infra-structure building tasks as the health alliance may contract with the Foundation to perform. These could include (but are not limited to) evaluating the need for professional manpower in local and regional markets; building infra-structure in underserved geographic areas or**

undercapitalized areas such as primary care and community based care.

- **Contract with one or more organizations linked to the national data network.**

- **Contract for the administration of consumer surveys that measure access to care, use of health services, outcomes and satisfaction and document shared decisionmaking.**

Planning grants would go to an eligible not-for-profit entity such as an existing Professional Foundation, a medical school, medical society or state agency. The geographic base for the Foundation will include (1) the natural referral area of academic medical centers as empirically defined by patient origin studies; (2) a population of sufficient size to study and reduce unwanted variations in the processes and outcomes for major operations such as bypass surgery.

STATE ROLE

As part of the quality management program, states assume responsibility to:

- Develop and implement plans to meet enrollment, access and quality standards established by the federal government.

- Assure that plans and providers meet essential national standards through licensure and certification procedures.

- Monitor the extent to which plans make the full range of benefits covered in the guaranteed package accessible to all population groups.

- Prepare statewide comparative reports on the performance of alliances.

- Establish in each alliance a premium check-off system through which up to $1 per participant can be allocated for support of a consumer advocacy program.

ROLE OF ALLIANCES

As part of the quality management program, health alliances:

- Resolve consumer complaints, grievances and requests to leave a health plan.

- Disseminate information related to quality of health plans, providers and practitioners and assure through

their negotiations with plans that performance and quality standards are met.

- Conduct consumer education programs.

- Provide technical assistance.

  - Organizations eligible to undertake this role include public-private partnerships, consortia led by academic medical centers, and others.

  - Technical assistance may include activities such as: fostering collaboration among health plans and providers; disseminating information about successful quality-improvement programs, disseminating practice guidelines and research findings; and providing educational courses and other forums for providers. Encourages the adoption of employee participation committees and other quality programs.

  - Technical assistance targets improving quality management practices. It is not designed to regulate or interfere with the administration of plans and providers.

  - Providers and health plans are not required to use technical assistance, although health plans are accountable for improving performance on national quality measures.

ROLE OF HEALTH PLANS

As part of the quality management programs, health plans:

- Measure and disclose performance on quality measures.

- Report on, maintain and improve the quality of care delivered by providers and practitioners.

- Meet national, uniform conditions of participation established by the National Health Board (See "Health Plans").

PERFORMANCE REPORTS

Annual performance reports for each health plan create a public system of accountability for quality and provide consumers with useful comparative information.

Performance report include information on the performance of alliances and health plans on as many as 50 measures of access to care, appropriateness of care, health outcomes, health promotion,

disease prevention, satisfaction with care **and success in promoting shared decisionmaking.**

The reports provide the results of a smaller number of quality measures for health care institutions, doctors and other practitioners if the available information is statistically meaningful. State performance reports include trends, results of national quality measures and of goals for national performance on access, appropriateness and health outcomes.

The following criteria determine the selection of national measures of quality performance:

- The measures reflect important aspects of care in terms of prevalence of illness, morbidity, mortality or cost.
- The set is representative of the range of services provided to consumers by the entities in question.
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- Performance on measures included in the set vary widely among the entities on the performance report.
- When the measures are outcomes of care, performance lies within the control of providers and adequate risk adjustment can be accomplished.
- The measures incorporate minimal standard for meeting public health objectives.

DEVELOPING INFORMATION FOR QUALITY MANAGEMENT

Health plans, providers and alliances report information required for the national quality management program through an electronic network linked nationally. The electronic networks have a contractual relationship with the regional quality consortia. Information required includes data related to enrollment, clinical encounters, consumer satisfaction and specific quality measures.

These centers electronically link regional quality programs, health alliances and plans, providing quality and utilization information for each health plan and provider as well as comparative information on other health plans and states.

To supplement routinely collected information, health plans gather clinical data specified by the national quality management

program from samples of medical records. Results from consumer surveys , in combination with other information, gauge access to health care, use of service, outcomes and satisfaction.

THE KNOWLEDGE BASE TO IMPROVE THE QUALITY OF CARE

To promulgate information about best practices and effective treatment approaches, the National Quality Management Program:

- Develops the survey instrument; states may add quality measures of local interest.
- Develops clinical practice guidelines, methodology standards, and an evaluation and voluntary certification process developed by the private sector.
- Operates a clearinghouse and dissemination program for practice guidelines.
- Disseminates information documenting clinically ineffective procedures and treatments.
- Supports research on topics central to quality management and improvement, including outcomes research, dissemination methods, ways of measuring quality and design of electronic information systems and new ways of organizing work systems.
- Establishes scientific standards and procedures for evaluating the clinical appropriateness of protocols used to manage health service utilization.
- Defines priorities for health-care evaluation research and recommends projects. The priorities target diagnoses associated with the highest levels of uncertainty in treatment decisions, widest variation in practice patterns, significant costs and incidence.

The Regional Professional Foundations:

- **Undertakes program to investigate the processes of care to identify and reduce sources of variation in mortality and other untoward outcomes.**
- **Participates in outcomes research in cooperation with PORTs and other research projects under the national outcomes research agenda.**
- **Develops and validates practice guidelines in concert with the national quality management board.**
- Contract with survey firms to conduct statistically valid surveys of sample populations to gather information related to consumer satisfaction, access to

care and health outcomes. Survey samples include over-sampling of populations considered to be at risk for inadequate health care.

- Disseminates practice guidelines that assist providers in achieving quality standards and underpin national measures of quality.

STREAMLINING REGULATORY ACTIVITIES

Minimum standards for health care institutions. the national quality management programs develops uniform standards for licensing of health care institutions that focus on essential performance requirements related to patient care. As they are developed, those standards replace current regulations except in areas of fire safety, sanitation and patient rights and without undermining recent reforms in nursing home care.

When the new standards are in place, agencies charged with certifying health institutions focus their attention on institutions with problematic records, responding to complaints and randomly selected validation sites.

By January 1, 1996, the National Quality Management Program completes demonstration projects for new performance standards and revises standards according to the findings. Demonstration projects evaluate the impact of these standards in assuring quality of care, reducing cost and burdens on providers.

Current standards are retained until new ones are tested, promulgated, evaluated and implemented. In the interim, government agencies responsible for licensing and certifying health care institutions coordinate inspections, reduce paperwork and control the number of inspections.

Medicare Peer Review Organizations. The peer review organization system under Medicare continues until the new quality system is implemented and the Secretary of the Department of Health and Human Services determines that Medicare enrollees are protected adequately though National Quality Management Program. PROs end at that time.

During the interim, the PRO program is streamlined. (See Administrative Simplification)

The Clinical Laboratory Improvement Act. Regulation of clinical laboratory testing refocuses to emphasize quality protection while reducing administrative burdens.

Regulation continues for labs that:

a) Perform a comprehensive menu of tests; or

b) Perform a large volume of tests (50,000 or

greater); or

c) Engage in critical testing (a test is critical if an answer is needed quickly or an error can result in serious harm to an individual); or

d) Conduct testing to monitor care while it is being delivered.

- Ease regulatory burdens on laboratories performing simple tests.

  Exempt laboratories performing waived and microscopy from all requirements under CLIA, including registration and payment of fees to the Department of Health and Human Services. Approximately 79,000 labs.

  Add more simple tests to the list of waivered tests.

  In accordance with recommendations by the Clinical Laboratory Improvement Advisory Committee (CLIAC), the physician-performed microscopy category are expanded to include tests performed by midlevel health care providers (e.g., nurse practitioners, physician's assistants, nurse midwives, etc.).

- Ease regulatory burden on laboratories performing moderately complexity tests.

  Create a new category of moderately complex tests performed using FDA-approved equipment subject to less stringent inspection requirements.

  By January 1, 1996, the Secretary of the Department of Health and Human Services issues a report on the extent to which regulation of laboratories performing moderately complex tests should continue. Within six months, the Secretary determines, based on the report, the need for cost regulation for these laboratories.

- Revise personnel standards to relieve in urban and rural areas.

  In accordance with recommendations by the CLIAC, individuals currently engaged in laboratory testing or supervision may continue to perform such testing in the absence of evidence of demonstrated poor performance.

  To address the concerns of rural and underserved areas, the Department of Health and Human Service modify personnel requirements for certain laboratory positions.

- Focus proficiency testing primarily on education.

Department of Health and Human Services only takes proficiency-related enforcement actions if a laboratory's performance is extremely poor or it has failed to take corrective action after proficiency problems are identified.

Department of Health and Human Services work with congressional committees to develop a modified approach to cytology proficiency testing.

- Streamline inspections.

  Department of Health and Human Services targets on-site inspections at high-volume, high-risk labs. Inspections are announced.

- Expand information and education activities.

  To eliminate confusion and misinformation about CLIA requirements, the Department of Health and Human Services works with professional groups to provide information and education.

Comments on Draft Legislation Specifications for Subtitle C--Health Research Initiatives

PAGE 1 - Line 8 - should read "PREVENTION" as opposed to the word, "PREVENTIVE", and delete "HEALTH SERVICES"

PAGE 1 - Line 21 - should read "entities" instead of "agencies".

PAGE 2 - Line 4 - add the word "prevention" after the word "supporting".

PAGE 2 - Line 5 - add "related to " after the word, research. Remove the word 'on'.

PAGE 2 - Line 6 - add "diseases" after the word recurrent.

PAGE 2 - Line 8 - remove the phrase "prevention research". Add the phrase, "to supporting" after the word "and".

PAGE 2 - Line 9 - add the phrase "related to health promotion and disease prevention" after the word "development".

PAGE 2 - Line 15 - We believe the correct designation for the new subsection should read (e) rather than (f).

PAGE 2 - Line 18 - add ", demonstrations and evaluation" after the word "research".

PAGE 3 - Line 1 - add the phrase "clinical and other health data and information systems;" after the semicolon.

PAGE 3 - Line 2 - add ";and medical liability reform." after the word "simplification".

PAGE 3 - Line 6 - add "quality measurement;" before the word "workplace".

PAGE 3 - Line 10 - add ", consistent with Sec. 913 (process for development of guidelines and standards)," before the word "and". Add the phrase ", consistent with Sec. 903 (dissemination)" after the word dissemination.

PAGE 4 - Line 10 - delete the word "development and".

Comments by Jim Kaple
V-A-1 through V-A-26
Draft of 10/18/93

V-A-10, line 4, after "approve" add "in consultation with DHHS."

V-A-10, line 6, after "the" add "National Center for Health Statistics or the Agency for Health Care Policy and Research for the"

V-A-10, line 7, after "may" add "request the addition of," and remove "add".
line 8. after "state" add "subject to state funding and in compliance with procedures established by the council."

V-A-10, line 10, after "Council" add "in consultation with DHHS."

V-A-13, line 5, after the word "shall" insert "employ research conducted by the AHCPR to."

V-A-14, line 20 after "shall" insert "employ the research conducted by AHCPR to."

V-A-15, line 20, change "section" to "title."
line 21, after "with" insert "AHCPR and."

V-A-15, line 7 after "shall" insert "in conjunction with the AHCPR."

V-A-16, line 12, after "research" insert "conducted by AHCPR."

V-A-17, line 5 after "research" insert "they support at AHCPR ."

V-A-18, line 1 after "shall" insert "coordinate and conduct through AHCPR the development of" and remove the word "develop."

V-A-18, line 8, Can these really be completed by January 1? (Policy question).

V-A-19, lines 1 to 8,
- Is Section (d) OK?
- Any role for AHCPR or IG?

V-A-19, Section 5009 - Is Regional Quality Consortia OK? (Policy question).

V-A-20, line 9, change "shall" to"may."
line 18, after "board" add "or the DHHS."
line 21, remove "performance" and replace with "Analyze and disseminate results."

V-A-21, line 3, through V-A-22, line 2. Is CLIA Policy OK?

Revisions 12:30 PM - 10/12/93

TITLE III—PUBLIC HEALTH INITIATIVES

****

Subtitle C—Health Research Initiatives

PART I—PROGRAMS FOR CERTAIN AGENCIES

SEC. 3201. BIOMEDICAL AND BEHAVIORAL RESEARCH ON PREVENTIVE ~~HEALTH SERVICES~~.

Section 402(f) of the Public Health Service Act (42 U.S.C. 282(f)) is amended—

(1) in paragraph (3), by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively;

(2) by redesignating paragraphs (1) through (3) as subparagraphs (A) through (C);

(3) by inserting "(1)" after "(f)"; and

(4) by adding at the end the following paragraph:

"(2)(A) The Director of NIH, in collaboration with the Associate Director for Prevention and with the heads of the ~~agencies~~ entities of the National Institutes of Health, shall ensure that such Institutes conduct and support biomedical and behavioral research on promoting health and

preventing diseases, disorders, and other health conditions.

"(B) In carrying out subparagraph (A), the Director of NIH shall give priority to conducting and supporting research related to child and adolescent health, chronic and recurrent Agency health conditions, reproductive health, mental health, substance abuse, infectious diseases, health and wellness promotion, environmental health, ~~prevention research~~ and to supporting related to health promotion and disease prevention resource development".

SEC. 3202. HEALTH SERVICES RESEARCH.

(a) AGENCY FOR HEALTH CARE POLICY AND RESEARCH.—Section 902 of the Public Health Service Act (42 U.S.C. 299a) is amended by adding at the end the following subsection:

"~~(f)~~ (e) RESEARCH ON HEALTH CARE REFORM.—

"(1) IN GENERAL.—In carrying out section 901(b), the Administrator shall conduct and support research demonstrations and evaluation on the reform of the health care system of the United States.

"(2) PRIORITIES.—In carrying out paragraph (1), the Administrator shall give priority to the following:

"(A) Conducting and supporting research on the appropriateness and effectiveness of alternative clinical strategies; the quality and out-

comes of care; ~~and~~ administrative simplification; and medical liability reform.

"(B) Conducting and supporting research on consumer choice and information resources; the effects of health care reform on health delivery systems; quality measurement; workplace injury and illness prevention; methods for risk adjustment; factors influencing access to health care for underserved populations; and primary care.

"(C) The development and dissemination of clinical practice guidelines and the assessment of the effectiveness of such guidelines.".

(b) HEALTH CARE FINANCING ADMINISTRATION.—Part A of title 11 of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by inserting after section 1110 the following section:

"RESEARCH AND STUDIES ON HEALTH CARE REFORM

"SEC. 1110A. (a) IN GENERAL.—In carrying out sections 1110, 1115, and 1875, the Secretary shall provide for research, ~~or~~ studies, and demonstrations on the reform of the health care system of the United States.

"(b) PRIORITIES.—In carrying out subsection (a), the Secretary shall give priority to providing for the following:

"(1) Conducting and supporting research or studies on the appropriateness and effectiveness of

alternative clinical strategies; the quality and outcomes of care; and administrative simplification.

"(2) Conducting and supporting research or studies on consumer choice and information resources; the effects of health care reform on health delivery systems; workplace injury and illness prevention; methods for risk adjustment; factors influencing access to health care for underserved populations; and primary care.

"(3) The ~~dissemination and~~ dissemination of clinical practice guidelines and the assessment of the effectiveness of such guidelines.".

PART II—FUNDING FOR PROGRAMS

SEC. 3211. AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out activities pursuant to the amendments made by part I, there is authorized to be appropriated $X,000,000 for each of the fiscal years ___. *[Such authorization is in addition to any other authorization of appropriations that is available for such purpose.]

SEC. 3212. OTHER FUNDING SOURCES.

(a) INITIAL ANNUAL BALANCE.—The Secretary shall, in accordance with subsections (b) and (c), ensure that as of October 1 of the fiscal year involved, there is available for purposes of carrying out activities pursuant

to the amendments made by part I the following amount, as applicable to the fiscal year:

(1) In the case of fiscal year ___, $___.

(2) In the case of each subsequent fiscal year, $___ increased by an amount equal to the product of $___ and the percentage by which the maximum amount of premimums authorized in section ___ has increased since October 1, ___.

(b) TRANSFERS FROM MEDICARE TRUST FUNDS.—

(1) DETERMINATION OF AMOUNT.—For purposes of complying with subsection (a) for a fiscal year, there shall be transferred to the Secretary from the funds established in sections 1817 and 1841 of the Social Security Act the following amount (in the aggregate), as applicable to the fiscal year:

(A) In the case of fiscal year ___, *[$xxx].

(B) In the case of each subsequent fiscal year, $xxx increased by an amount equal to the product of $xxx and the percentage by which the maximum amount of premimums authorized in section ___ has increased since October 1, ___.s

(2) CERTAIN ALLOCATIONS.—With respect to the amount required under paragraph (1) to be

transferred for a fiscal year from the funds established in sections 1817 and 1841 of the Social Security Act, the Secretary shall determine the allocation of such amount among the funds.

(c) CONTRIBUTIONS OF REGIONAL AND CORPORATE ALLIANCES.—

(1) DETERMINATION OF AMOUNT.—For purposes of complying with subsection (a) for a fiscal year, regional and corporate alliances under this Act shall, subject to the provisions of this subsection, make available to the Secretary an aggregate financial contribution in an amount equal to the following:

(A) In the case of fiscal year ___, *[$xxx].

(B) In the case of each subsequent fiscal year, $___ increased by an amount equal to the product of $___ and the percentage by which the maximum amount of premimums authorized in section ___ has increased since October 1, ___.

(2) ALLOCATION AMONG REGIONAL AND CORPORATE ALLIANCES.—With respect to the aggregate financial contribution required under paragraph (1) to be made for a fiscal year by regional and corporate alliances under this Act—

(A) the portion required to be contributed by regional alliances is the percentage constituted by the ratio of the total health expenditures of regional alliances to the combined total health expenditures of regional alliances and corporate alliances; and

(B) the portion required to be contributed by corporate alliances is the percentage constituted by the ratio of the total health expenditures of corporate alliances to such combined total health expenditures.

(3) MANNER OF COMPLIANCE.—With respect to the portion required pursuant to paragraph (2) to be contributed for a fiscal year by regional alliances and corporate alliances under this Act, resepectively, the following applies:

(A) In the case of regional alliances, the portion so required may be generated by such alliances through premiums paid by employers and individuals for health plans of the alliance.

(B) In the case of corporate alliances, the amount of such portion shall (for purposes of compliance with subsection (a)) be transferred to the Secretary from amounts paid under section ___ (relating to assessments on corporate

alliances), and such transfer shall be considered to be the portion so required.

(4) CONTRIBUTIONS OF INDIVIDUAL REGIONAL ALLIANCES.—With respect to the financial contribution required pursuant to paragraph (2)(A) to be made for a fiscal year by regional alliances under this Act, the portion required to be contributed by a regional alliance is the percentage constituted by the ratio of the health expenditures of such alliance to the total health expenditures of regional alliances.

(d) DEFINITIONS.—For purposes of this subtitle:

(1) The term "initial annual balance", with respect to a fiscal year, means the amount required in subsection (a) to be made available as of July 1 of the fiscal year.

(2) The term "health expenditures", with respect to a regional or corporate alliance under this Act, means the amount expended by the health plans of the alliance to provide health services in compliance with this Act.

Will ↑ Primary care by 50% by Yr