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I. BACKGROUND

CURRENT PROBLEMS

A. Uncertainty pervades medical care.

- In many areas of medicine, we simply don't know what works best. [Tab I, Wennberg, 1990].

  - The scientific evidence for the effectiveness of many -- perhaps most -- of the most common treatments is either mixed or nonexistent.

  - This results in **wide variations in professional opinions and in medical practice**. For instance, Bostonians receive almost twice as much hospital care as New Haven residents, with no discernable impact on their health.

- This uncertainty can confound attempts to manage health care competition and to control health care costs.

  - When we don't know what works best to treat a particular illness, it's impossible to determine which provider treats that illness best -- to measure that provider's "quality of care."

  - A significant number of costly procedures have been found to be either inappropriate or of uncertain value, in managed care settings as well as in fee-for-service medicine. [Tab I, Bernstein et al, 1993; Leape et al, 1993; Hibourne et al, 1993].

- Too little research is targeted toward reducing that uncertainty. [Tab I, Wennberg, 1990]

  - Most efforts to evaluate new treatments do not test them in realistic settings, or compare them to existing therapies.

  - Many medical interventions have not been assessed at all, especially medical treatments that do not use new devices or drugs.

- Even well-documented research findings about appropriate treatments and patterns of care frequently fail to reach practicing health care providers or aid them in making clinical decisions. [Tab I, Kosecoff et al, 1987]. This leads to:

  - Excessive use of unnecessary and inappropriate services.

  - Under use of needed and appropriate services, such as preventive and prenatal care or follow-up visits for chronic illnesses.

  - Unnecessary deaths, illness and disability that might have been prevented with appropriate care. [Tab I, Healthy People 2000]

B. A marketplace depends on broad availability of information to compare products. That information has been lacking in health care. [Tab I, Office of Technology Assessment, 1988].

- Until recently, physician and hospital groups have opposed publication of comparative information on prices and indicators of quality.

- Universal agreement on the best measures of quality has been lacking.

- Health care providers are frequently unaware of their own patterns of practice, and how they compare to others'.

- Consumers are often not informed about various treatment options and their risks and benefits. [Tab I, Wennberg, 1990]

C. Techniques used to improve quality have been ineffective. [Tab H, Institute of Medicine (IoM), 1990]

- Most quality assurance activities undertaken by health care institutions, groups or external reviewers **do not prevent, identify or correct** quality problems

  - These methods focus excessively on processes of quality assurance, such as quality committee meetings, case review or incident reporting, rather than on achieving actual improvement.

  - They focus on inspection of individual cases to detect unusual events after-the-fact, and on identification of "bad apples" among practitioners, rather than on identifying and correcting the root causes of problems within an institution.

- Most quality assurance and improvement efforts have focused on hospitals, rather than on the physicians' offices and clinics where most care is delivered.

D. The current regulatory systems to assure quality are perceived as creating more burden on providers than benefits to consumers.

- Standards for health care facilities and HMOs include more proxies for quality than measures of health care and patient outcomes.

- Facility standards include hundreds of pages of detailed requirements for nursing aide qualifications, square footage of bedrooms, medical record-keeping and the like.

- Standards for HMOs include requirements on enrollee composition, and disenrollment on demand, which hinder health plan operations.

• Facilities and HMOs often undergo multiple surveys each year.

E. Current protections for consumers vary by State, and they are inadequate to counter the powerful incentives for underutilization of care that are built into health reform.

• Facilities and HMOs that opt not to participate in Federal programs are subject to widely varying state licensure programs.

• Other types of health plans, such as preferred provider organizations and indemnity insurance, have been subject to virtually no regulation intended to protect quality of care.

RECENT DEVELOPMENTS AND PROMISING SOLUTIONS

A. Recently-developed tools can now support a new approach to assuring quality of care. [Tab H, Jencks and Wilensky, 1992.]

- Large health care data sets are becoming available for analysis, and there are a number of efforts to develop data sets targeted specifically for quality assessment. [Tab C: GHAA summary; "Coalition Quality Initiatives"].

- Powerful computing tools and techniques are enabling routine, inexpensive analysis of these data sets.

- Research using these data sets can assess the effectiveness of medical treatments and reduce medical uncertainty.

  - Congress established the Agency for Health Care Policy and Research (AHCPR) in 1989 to increase support for such research.

  - The total Federal budget for such research has grown to $150 million in FY 1993.

- A new effort to develop scientifically-based practice guidelines has gathered steam.

  - AHCPR has developed 6 comprehensive guidelines on treatment of important medical conditions. 4 more are due out in FY 93, and 10 annually after that. [See samples in Tab J].

- The American Medical Association and its associated specialty societies are leading an effort that has developed hundreds of guidelines, though these are of variable quality.

• Due to these efforts, measurement of quality in an objective, science-based fashion is becoming feasible.

- Techniques for measuring appropriateness of care and health outcomes using data have been developed. [Tab E]

- So have survey methods to assess consumer perceptions of health status, health behavior and satisfaction; [Tab E, survey instruments and reports]

- Lists of quality measures have been compiled, and their ability to distinguish true differences between providers assessed. [Tab C: Siu 1991; HEDIS, 1993]

B. This new, information-based approach is being piloted in a variety of Federal-, state-, community- and industry-based programs around the country. [See Tab D for examples.]

• Business groups are now joining with providers and managed care plans, both in localities and nationwide, to produce and publish comparative quality information. Employers will use this information to select providers and plans on the basis of both quality and cost.

• Dozens of States, according to the National Association of Health Data Organizations, have formed health data organizations that publish comparative information on providers' on measures of quality and cost.

- A mass-market magazine providing consumers with helpful articles on treatments and comparative information on physicians and providers is currently being test-marketed in Wisconsin. [Health Pages]

C. Programs have been established to help consumers sort through the new wealth of information on health insurance, and to protect their interests in other ways.

- In 1990, Congress established programs to counsel Medicare beneficiaries on the purchase of Medigap (Medicare supplemental) insurance and long-term care insurance.

- Under the Older Americans Act, since the late 1970's, each State has a ombudsman's program for residents of long-term-care facilities.

- 1992 amendments to that Act will provide for a comprehensive system of counseling and assistance for all forms of health insurance for older Americans.

D. Minimum standards for facilities and health plans are moving toward assessment of actual performance rather than detailed structure and process standards.

- In 1987, Congress reformed Federal standards that nursing homes must meet to participate in Medicare and Medicaid.

  - The new requirements are centered on improving the functional status of nursing home residents.

  - Under the new regulations, according to the Health Care Financing Administration (HCFA) use of physical and chemical

restraints in nursing homes has been cut nearly in half, from 39% of residents in 1990 to 21% in 1992.

- The Joint Commission on Accreditation of Health Care Organizations (JCAHO) has been moving its accreditation for hospitals toward use of specific quality indicators. [Tab B, JCAHO].

- The National Committee for Quality Assurance (NCQA) new accreditation standards for HMOs focus on quality measurement. [Tab F, NCQA].

E. Continuous quality improvement principles used in other industries are beginning to be applied in health care. [Tab G].

- These include efforts to collect data systematically, measure a broad set of outcomes, identify areas for improvement, improve processes, and regularly assess the effect of those changes on the outcomes measures.

- Successful examples of this approach include:

  - Latter Day Saints Hospital in Salt Lake City cut its rate of deep postoperative infections in half, through studies of surgical antibiotic use. [Tab G, Frontiers, 1991].

  - West Paces Ferry Hospital in Atlanta reduced its caesarian section rate from 22% to 12% of births. [Tab G, Nelson, 1992]

- The JCAHO and NCQA have implemented new standards that focus on quality improvement. [Tab B, JCAHO; Tab F, NCQA].

II. Issues

A. As incentives to control costs are put into place, the new system must guarantee quality of care.

1. The information on quality critical for choosing plans, practitioners, providers and treatments is not yet available.

a. Consumers

- Need comprehensive, accurate and up-to-date information to make informed decisions about health care plans, select practitioners, and become more active in making decisions about their own health care.

- **For this to happen, the new system must provide new information and assistance in interpreting that information, and must also assist consumers in understanding and using the system itself.**

b. Practitioners

- **Need immediate access to valid information on what works best in health care.** The flood of information from pharmaceutical company representatives, professional organizations and the mass media is often biased or incomplete, and is not easy to judge or use in every day practice.

- The new system must provide better and more organized information on **appropriate** use of services.

- The new system must reduce the burden of regulation so that practitioners can focus on the delivery of care.

c. Purchasers

- Need to have information that allows them to make decisions based on **quality** as well as price. This information must be **comparable across plans**.

2. The new system must be designed to protect consumers from substandard care.

   a. The system must be able to identify incompetent or impaired providers, and either restore them to appropriate practice or remove them.

   b. The system must assure that resource constraints do not prevent consumers' access to needed services.

   c. The new system must foster an **improvement** in the average level of care without imposing a specific approach from the outside.

   d. The system must allow innovation in activities to improve quality.

      1. It must not impose a surveillance system that unnaturally diverts resources away from quality improvement.

      2. The "excellent" performers must be included in the system to lead the way.

B. Without careful planning, collecting the range of quality of care information needed for informed choice and accountability could become extremely burdensome.

   1. **The challenge is to identify measures that can be used today, while research continues to develop better measures.**

   2. Information on the health of the population and the effectiveness of the system will require data from a variety of sources.

   3. The need for information must not outstrip the availability of measures nor burden the system with unreasonable data collection.

C. The market cannot provide solutions to all quality issues.

1. Regulation will be necessary to ensure a minimum level of quality and efficient market function, particularly in areas where competition is absent, and during the transition, when the quality measurement and competitive forces will not be fully in place.

2. The current regulatory environment is not successful

   a. It involves over-regulation (overlapping Federal and State mandates in areas of licensure and safety) and micromanagement (telling labs and providers how to run their quality management programs).

   b. Producing the paperwork related to unnecessary regulation diverts resources away from delivering care and improving quality.

3. Standard reporting of performance should drive participants to improve performance on the reported measures.

   a. The new system can focus on measures that are important for protecting quality and facilitating choice.

   b. If quality measures are on target, we have valuable information. If they are not, we fail to protect consumers, assist practitioners and purchasers, and assure accountability.

   c. But any report will cover only a small fraction of plan activities. Extrapolation about overall quality of care must be done with caution.

D. GOALS FOR REFORM

These recent developments provide a strong platform for health care reform to meet its goals for quality:

- To provide information to support consumer choice
- To protect consumers
- To improve the quality of care and services, and
- To be accountable to policy makers and the public.

III. RECOMMENDATIONS AND RATIONALE

A. SUMMARY OF WORKGROUP PROPOSAL

Recommendations:

The ultimate success of health care reform depends on the ability of the new system to **contain costs** while **protecting quality**. The new system will:

- **Provide standardized reporting of information on quality.**
- **Foster quality improvement by clinicians and institutions.**
- **Ensure basic protections through Conditions of Participation**.
- **Strengthen and streamline existing quality oversight mechanisms.**
- **Bolster the knowledge infrastructure** for quality care through evaluation research, technology assessment, and patient care guidelines.

B. ORGANIZATION OF THE QUALITY MANAGEMENT SYSTEM

Recommendations:

The new system is decentralized and responsibility for quality is embedded at every level and every organization.

- **Consumers will:**
  - Be responsible for reporting information relevant to quality of care.
  - Use comparative information on plans, health care facilities, practitioners and treatments to inform their decisionmaking.
- **Practitioners will:**
  - Be held accountable for their comparative performance on quality measures.
  - Work cooperatively with health plans to improve the quality of care.
- **Health care facilities will:**
  - Be required to meet nationally uniform minimum, performance-based standards.
  - Be held accountable for their performance on quality measures.

- Continually improve the quality of their care.

- Use comparative information on plans, practitioners and treatments to inform their decision-making.

- **Health plans will:**

  - Protect consumers from poor quality by meeting Conditions of Participation,

  - Measure and disclose their performance on quality measures

  - Disclose all material information, and

  - Report on, maintain and improve the care their providers and practitioners deliver.

- **Health alliances and other purchasers will:**

  - Protect consumers by using information on quality of care in selecting and negotiating with plans.

  - Handle appeals of consumer grievances and requests to disenroll.

  - Collect and update enrollment data.

- **States will:**

  - Monitor the quality of their State's health care system

- Prepare comparative Quality Reports on plans, providers and practitioners
- Survey consumers
- Establish health ombudsmen's offices
- Transmit collected data and report state performance to the Federal government
- Provide technical assistance to providers, health plans, and practitioners
- Assess health plan compliance with Conditions of Participation
- Assess facility compliance with minimum licensure standards.

• **The National Quality Program (NQP)** will:

- Develop a core set of quality measures and consumer survey questions
- Set goals for performance on those measures
- Support research, technology assessments and pilot projects to undergird quality measurement
- Develop performance-based licensing standards for facilities
- Set Conditions of Participation for health plans

- Set standards for, fund and monitor State performance

- Evaluate the impact of health reform on quality regularly

• **The National Quality Advisory Council** appointed by the President will:

- Oversee the National Quality Program and its annual reports on performance of the national and state programs.

- Define the core set of measures annually and establish a five year priority list for future measures to be included in the core set.

- Review all state waivers and development of performance-based licensing.

Rationale:

a. Quality assurance and improvement requires commitment through out the system. Poor quality usually results from failures in the system not incompetent or uncaring individuals.

• Under reform State Health Alliances and health plans will be accountable for the quality of care delivered to their respective population.

b. Consumers must have the assurance that quality of care will not vary from state to state, therefore, the workgroup recommends:

• Standards for care and service set by the Federal government, and

• Federal oversight of State performance in assessing compliance with those standards.

c. Health plans and health alliances will have financial pressures that might lead to quality problems, especially under service. Therefore, we recommend that **quality oversight be conducted**, and Quality Reports be prepared, **by an agency independent of the plans and alliances** -- the State Quality Program.

C. STANDARDIZED REPORTING OF INFORMATION ON QUALITY

Recommendations:

The new health care marketplace will be driven by information. Our recommendations ensure that a great deal of new, understandable, comparative information will be available to facilitate choices of health plans, facilities, practitioners and treatments, and monitor the performance of the system as a whole.

- The National Quality Program will develop and pilot test a core set of measures that apply to all plans, facilities and/or practitioners nationwide.

- **Measures will be developed that allow comparison of performance** along four aspects of quality:

  - Access to care

  - Appropriateness of care

  - Outcomes of care

  - Consumer satisfaction

- **States will publish Quality Reports** that compare the performance of health plans, facilities and practitioners along the national core set of measures, as well as along measures of the state's choice. [See attached illustrative quality report]

- State health ombudsmen will assist consumers in interpreting this information.

- The National Quality Program will publish a national report to compare State performance along quality measures.

- Plans will be held legally accountable for the accuracy of their data. States will conduct some audits to verify data accuracy.

- **In selecting measures, the NQP will adhere to high scientific standard, while minimizing collection burden:**

  - The set of measures will be representative of the range of services provided by the entity in question,

  - Pilot testing shows them to be reliable and valid

  - Pilot testing shows performance on the measures to vary widely.

  - The data needed are obtainable without significant burden,

- Measures will change over a period of years in order to cover a wide range of quality issues, reflect medical progress and assure that measures remain representative of plan performance

- Measures have already been developed that can serve as a starting point. They will be refined over time by the National Quality Program.

Rationale:

a. **The cornerstone of health care reform is informed decisionmaking.** (Tab C, OTA, 1988; Tab I, Wennberg, 1990)

- The current availability of information to facilitate choice and protect quality is limited.

- The customers for this information have little experience using what is available.

- Plans and providers need accurate data on their performance to gauge their quality of care, identify areas for improvement and measure their progress. (Tab C, Siu, et. al., 1991)

b. The quality measures must meet the highest standards and change frequently.

- If the measures are on target, we have valuable information. If they are not, we fail to protect consumers, assist practitioners and purchasers, and assure accountability.

- Plans will divert resources to improving performance on these measures. If the measures are static gaming will occur.

c. If the measures are too burdensome to collect, the system will fail.

D. QUALITY IMPROVEMENT

Recommendations:

- Health care reform will **foster effective and efficient internal quality assurance and quality improvement efforts** by all health plans and facilities in the system. These programs will:

  - Address problems of overuse, under use and poor technical and interpersonal performance

  - Endeavor to identify and correct problems involving all settings, types of clinicians and patients within the plans

  - Strive to eliminate poor care, enhance the average level of quality over time and identify superior performance, and

  - **Be accountable by documenting and reporting measurable improvement in quality.**

- To facilitate these efforts, **States** will arrange for voluntary **technical assistance programs** funded by Federal grants which may include:

  - Fostering collaboration among plans, providers, and consumers to deal with common problems and share information on improvement

  - Formation of clearinghouses that maintain information on successful improvement projects, quality measures, practice guidelines, and research findings

- Feedback of data on performance, particularly by means of computerized guidelines and expert systems

- Medical record audits to help providers understand problems

- Advice on clinical or management strategies that have proven effective in improving performance, and

- Other approaches developed locally or statewide.

Rationale:

a. Quality improvement is most likely to be achieved when it is **internally motivated**. The workgroup believes protecting quality will be accomplished most expeditiously by providing quality improvement **tools, not rules**. (See Tab G, Berwick, 1989)

- Specific **structures and procedures for quality assurance and improvement are not specified.**

b. External incentives to improve quality will expedite the transition to a quality system that is internally motivated. **Holding plans accountable for the results of the care delivered and for achieving quality improvement are appropriate external incentives.**

- This condition requires plans to demonstrate continuous improvement in the quality of care through results such as improved health outcomes and increased patient satisfaction.

c. **Solid, meaningful quality improvement (QI) efforts are taking hold across the country.** (Tab G, Frontiers, 1991)

- Many established health care organizations and institutions are implementing performance based quality improvement programs.

- These recommendations assist their efforts by removing some of the administrative and regulatory barriers to these plans.

d. Not all health plans are so far along. **Most plans will require assistance to mount credible internal QA/QI efforts.**

E. CONDITIONS OF PARTICIPATION

Health plans must meet the following nationally uniform Conditions of Participation in order to participate in health care reform:

1. **Fiscal soundness**

2. **Truth-in-marketing**

3. **Credentialing** of practitioners and facilities. Every 2 years, plans must:

   - Check providers against national databases.

   - Consider credible complaints against the providers.

   - Drop providers that consistently fail to meet quality standards or are responsible for fraud or mismanagement.

4. **Enrollee Rights and Responsibilities.** A plan must:

   - Disclose to consumers all material information regarding the plan and their rights and responsibilities within it.

   - Provide due process for enrollees to appeal denial, termination or reduction of coverage.

   - Allow state health ombudsmen to assist consumers in their appeals.

   - Allow unresolved complaints to be appealed to the Health Alliance then the State.

5. **Confidentiality.**

6. **Complaints.**

   - A plan must investigate and attempt to resolve complaints.

7. **Disenrollment for Cause**.

   - Enrollees must be permitted to disenroll at any time for good cause.

- State health ombudsmen may assist consumers in this process.

- The purchaser is responsible for ensuring there is no gap in coverage.

8. **Utilization Management.** A plan must disclose all its protocols for controlling utilization and costs, including:

- Methods used to manage the network of providers, such as the selection criteria and internal performance standards.

- Compensation methods for providers, such as capitation;

- Incentives to providers to control utilization;

- Utilization review criteria - criteria by which health care services are determined to be inappropriate; and

- Protocols for managing the care of high-cost patients.

9. **Internal Quality Management.** A plan will be held accountable for measurably improving the quality of its care and service, and for correcting problems.

10. **Data Management and Reporting.** A plan must maintain the data required to determine measures for the quality report and must report applicable data to the State.

Rationale:

a. Under health care reform, health plans will be accountable for providing all necessary health care to their enrollee populations. **Therefore, they must be held accountable for meeting quality goals relating to consumer protection, consumer information to support choice, and quality improvement.**

b. Consumers' trust in the new health care system must be built. Consumer groups advocate strong protections that assure the system meets minimum standards.

c. Certain kinds of information is particularly reassuring to consumers. For example:

- Information on providers and treatments

- Plan utilization management strategies that might limit access to care.

- Information on the standards to which the plan holds practitioners

d. Consumer groups (See Tab B, Consumer Coalition) advised that consumers must be able to protect themselves through:

  - Grievance procedures
  - Appeals of unresolved grievances
  - If all else fails, disenrollment.

e. In order to assure consumers an acceptable level of protection, national standards must encompass and move beyond the various consumer protection and quality assurance standards in place for managed care organizations today. (Tab F)

f. Plans that fail to meet these standards should not be permitted to provide coverage under health reform. Therefore the standards must be conditions of participation.

F. STRENGTHENING AND STREAMLINING CURRENT QUALITY ASSURANCE ACTIVITIES

The Health Care Financing Administration (HCFA) now conducts three quality assurance programs that provide basic consumer protections. However, all three of these programs have been criticized as placing undue burden on providers and practitioners.

Health care reform will build on these three programs to achieve the quality goals of consumer protection, quality improvement and accountability. Each program will be significantly **strengthened** and **streamlined**.

These programs are:

1. **Minimum Standards for Health Care Facilities**. The floor for health care quality in the United States is established in licensure and certification standards set by the State and Federal governments. (Tab H, IoM, 1990)

   - **These standards will be revised to be more effective and based on performance.**

     - The 1987 **Nursing Home Reform** requirements are performance based and **will be retained** as is. (Tab B, National Citizen's Coalition)

   - **Current standards will be retained until new ones have been fully promulgated, pilot-tested, evaluated and implemented.**

   - The process for assessing compliance will be revised to **reduce the burden on facilities**.

     - Multiple inspections by government agencies will be eliminated.

2. **Medicare Peer Review Organizations (PROs).** The PRO program, the primary Federal effort to monitor the quality of health care provided to Medicare patients, **will be retained**.

   - This program is already engaged in an effort to make itself more efficient, effective and accountable; this new effort is highly compatible with health care reform. (Tab H, Jencks and Wilensky, 1992)

- PROs will pilot test the quality management techniques proposed under reform.

- The program's effectiveness will be regularly evaluated.

3. **The Clinical Laboratory Improvement Amendments of 1988 (CLIA)**. Under CLIA, all labs in the U.S. are regulated. (Tab H, CRS) **The burden and cost of this program will be significantly reduced.**

- Labs performing only waived tests will no longer pay fees and file registration forms.

- Maintain regulatory scrutiny of labs that --

  - Conduct a comprehensive menu of tests
  - Conduct a large volume of tests
  - Engage in cytology tests such as Pap smears
  - Conduct tests to monitor care while it is being delivered, such as dialysis labs.

- Simplify standards to focus on quality control procedures, test accuracy and specimen handling.

- Immediately eliminate the requirement that all labs engage in proficiency testing.

- As of the second year of reform, eliminate regulation of any other types of labs for which experience shows regulation to be unnecessary.

<u>Rationale</u>:

a. **It is critical to maintain a floor for health care quality, below which no health care provider is permitted to fall.** This floor is set by licensure and certification for most facilities, by CLIA for labs, and is monitored for Medicare beneficiaries by the PROs.

b. The current regulatory system has improved health care delivery in some areas. And there have been some notable successes in improving quality of care, for instance:

- Nursing home use of restraints were cut nearly in half between 1990 and 1992 as a result of nursing home reform (HCFA, unpublished data);

- Facilities for the mentally retarded were transformed from human warehouses to providers of active treatment to all residents as a result of new standards in the 1970s;

c. Many believe such examples are exceptions rather than the rule, and that the quality of care overall has not improved as a result of existing standards. (Tab H, IoM, 1990) Problems include:

- The standards often focus on the process of providing care not on patient outcomes.

- **The regulations are criticized by consumers and providers as being ineffective, burdensome, costly and inconsistently enforced.**

- Providers say the cost and burden of compliance stifle creative efforts to improve quality.

- PROs have focused on small problems and single cases rather than the big picture.

d. Consumer groups and experts advise:

- **Maintaining consumer protections are not removed unless they have been demonstrated to be ineffective or have been replaced by a program that is demonstrably more effective.**

- Using standards based on performance.

- Making the quality assurance system for health care facilities more efficient to reduce the burden on practitioners and facilities is reduced.

- Providing facilities are provided incentives to internally, continuously and measurably **improve** the quality of their care.

G. GUIDELINE DEVELOPMENT, TECHNOLOGY ASSESSMENT AND CLOSELY RELATED RESEARCH

Recommendations: The Federal Government will --

- Annually list priorities for measuring and assessing the quality of care, over the next 5 years.

- **Set research priorities will include:**
  - **The greatest medical uncertainty in treatment,**
  - **the greatest variation in practice patterns,**
  - **Significant cost to the health care system, and/or**
  - **Significant burden to the population;**

- **Support research on methods central to quality improvement.**

- **Support health care evaluation research** (including medical effectiveness research, clinical trials of therapies, and other projects).

- Funding for such projects is recommended to be increased.

- Establish non-binding, science-based standards for clinical practice guidelines and procedures for evaluating guidelines according to those standards, and evaluate any guidelines voluntarily submitted for review.

- Establish non-binding, science-based standards for and develop procedures for evaluating the clinical appropriateness of utilization management protocols.

Rationale:

a. Most of the variation in practice patters is due to uncertainty about diagnostic indications or effectiveness of particular treatments. Research is needed to reduce this uncertainty and to **systematically improve health care** in America.

b. Better information on appropriate practice as well as effective treatments and technologies will support consumer choice and lead to quality improvement.

c. The success of our efforts to assess and improve quality will depend on the quality of the tools we use.

d. Setting priorities for research, unlike the current, largely ad hoc process for approving research proposals, will ensure that **major areas of medical uncertainty that have a great impact on Americans' health will be addressed**.

IV. Questions and Answers

TYPICAL QUESTIONS THAT COULD BE RAISED BY CONSUMERS, PRACTITIONERS, PLANS, PROVIDERS AND PURCHASERS

Reporting Standardized Quality Data

1. How can we be sure that the Report on Quality Measures won't be too burdensome and that important aspects of quality are measured?

a. The battery of measures will be selected by the National Advisory Committee. The membership will be balanced to include:

- purchasers who will favor more information
- plans who will be particularly concerned about the burdens of data collection
- providers who may be most sensitive to the technical aspects of care
- patients who may be more concerned about the interpersonal aspects of care, and
- quality measurement experts who may be more sensitive to methodologic issues in measurement.

b. We expect that the expertise on the committee and the balance in membership will help optimize the selection of measures in the battery.

2. Won't providers see the report on quality of care as punitive?

a. Several aspects of the program will reduce this possibility.

- Quality improvement will be adopted as a condition of participation. Measurement is the first step in this process and providers will be involved in the measurement.

- Technical assistance will be offered to plans who wish to improve performance by a **nonregulatory agency.** This will send a clear message about the non punitive intent.

- Quality measurement will be done by the plans themselves. This will convey the message that they are part of process, not just the object of it.

3. The limited number of measures in the report will make it difficult for consumers to make an informed choice. This is especially true if the measures are uncorrelated and present a confusing picture.

a. It is true that only a portion of the types of care delivered will be measured and that performance of plans may differ across measures so we need to be modest in our claims.

b. Although measurement may be inadequate to make fine distinctions, it still may be sufficient to identify plans that are delivering truly superior care or very inferior care.

- We envision that the use of the quality information may be similar to that used by Consumer Reports. Products are rated numerically, but users are advised that small differences in ratings are not meaningful. Only products which stand out are grouped separately.

c. Even if measurement doesn't provide tremendous aid for choice, it is still valuable.

- Trends will tell us whether we are improving care over time.

- Plans that learn the methodology of measurement can use this skill in improvement activities.

d. A national measurement system will send a strong message about the importance of measurement and its role in quality improvement.

4. How will public health reporting fit in and how will public health concerns be balanced?

a. Public health reporting will continue. Public health trends will provide insight into things we should measure as part of the quality report.

- For example if the incidence of active tuberculosis increases, quality measures might be developed to assess whether plans' testing procedures and prophylactic treatment is appropriate.

b. Public health concerns will drive the initial selection of measures and the development of new measures.

- The Advisory Committee will have among its principal goals the reduction of the illness burden in the country.

- Conditions which have an important impact on the health of a large number of persons will be preferentially chosen.

Quality Improvement

5. Do we really need a state-run technical assistance program, won't it be too bureaucratic?

a. These activities are very important because they send a message that quality improvement is vital.

b. The state will merely oversee these activities. We expect technical assistance to be carried out by a variety of different organizations including private sector consulting firms, foundation inspired public-private partnerships, consortia of academic medical centers, innovative state agencies etc.

c. The large number and diversity of organizations involved will foster innovation and increased understanding about the effectiveness of different approaches to quality improvement.

6. Don't you think that requiring plans and facilities to meet all these prescriptive conditions will stifle innovation, and conflict with the goal of continuous quality improvement quality under health care reform?

a. These goals should not conflict. Unlike some past and current standards for facilities and health plans,

- the standards imposed under the mature reformed health care system will be based on actual performance,

- rather than on restrictive detailed mandates about structures and processes -- such as staffing levels, enrollee composition and quality assurance committees.

b. The quality management proposal also provides incentives and technical assistance for plans and facilities to improve the quality of their care.

7. Doesn't the emphasis on continuous quality improvement activities develop voluntarily within health plans, place undue reliance on the good will of health plans and provide inadequate consumer protection?

a. Many studies show that meaningful improvement occurs when health care providers are involved in and committed to a process of improvement that is relevant to their own patients and experiences. This is difficult to legislate or impose from the outside. We will require disclosure of the results of quality improvement, however, so this is not an entirely voluntary process.

b. Furthermore, this is not the only mechanism for quality measurement and assurance under health care reform. We have included additional provisions, such as conditions of participation, the requirement for ombudsmen, and the gathering and publishing of standardized quality measures, that will provide adequate consumer protection.

8. Are the States capable of mounting the type of technical assistance contemplated in this proposal?

a. Some States we will be able to because they have more experience and existing resources to draw upon than others. However, the States have the option of contracting with private sector groups to provide the necessary expertise.

b. In addition, technical assistance from the Federal level will also be available. One important role of the Federal government will be to gather "lessons learned" from quality improvement initiatives and disseminate that information to interested organizations.

9. Is there any evidence that internal quality improvement efforts in health care settings are actually effective?

a. Yes. For example as a result of one hospital's dedication to quality improvement (See Tab G, Nelson 1992):

- C-section rates were cut from 22 percent to under 12 percent in three years;
- the efficiency of treating patients with chest pain improved so that the percentage of patients admitted who actually had a heart attack vs. those patients who did not have heart attack related pain increased from 28 percent to 68 percent. This led to savings to one customer of $330,000 in one year;
- the percentage of non-RN duties that RNs perform was reduced from 40 percent to 24 percent, saving $250,000 annually;
- Annual operating margin increased from $9 to $20 million.

10. Is the supply of persons skilled in QA/QI approaches and methods sufficient for the program you propose?

a. We believe that the current supply of persons, combined with technical assistance, is adequate to begin.

b. However, we need more health professionals trained in epidemiology and statistical analyses, as well as group processes and the identification of meaningful hypotheses for quality improvement. Fortunately, there already exist some relevant training opportunities and professional groups.

11. Haven't past attempts at quality improvement been largely ineffective?

a. I don't think one can generalize from experiences 15-20 years ago to the present for several reasons.

Earlier efforts have been more externally imposed and not focused on results and quality **improvement**.

We have better measures and information systems today than we did in the past, and a large cadre of health professionals skilled in quality measurement.

b. The competitive health care system we envisage emphasizes competition based on value, quality, and cost.

- It contains mechanisms to hold plans accountable for good health care outcomes and has better information about medical effectiveness than previously existed.

Consumer Protection through Conditions of Participation

12. How can I be sure that restrictions on my right to choose doctors and hospitals won't harm the quality of my care?

a. Health plans will be required to ensure that the doctors, hospitals and other health care providers they use have been licensed or certified as meeting basic State and Federal standards for the quality of care.

b. They will be required to reverify these credentials at least every two years, and to check any disciplinary actions, malpractice history and credible complaints each time.

13. What if the health plan I choose makes me wait a long time for an appointment or necessary treatment, even when I am sick?

a. You can file a complaint with the plan, which will be required to investigate and resolve the complaint with the speed appropriate to the urgency of your medical situation. The State ombudsman's office can help you investigate and resolve the complaint.

b. If the plan does not resolve the complaint to your satisfaction, you can appeal to your health alliance or employer, which must attempt to resolve the issue.

- If all attempts to fix the situation fail, you can ask the health alliance to let you disenroll immediately "for cause."

- The health alliance is required to enroll you in another plan of your choice and to ensure there is no gap in coverage.

14. Setting truth-in-marketing standards is not enough to protect consumers. Fraudulent information and deceptive marketing are likely to be rampant. Why haven't you simply banned plans from giving out any information that hasn't been approved by the State?

a. Competitive markets work best when consumers have a wide variety of information on which to base their choices.

- Rather than banning disclosures, the health reform plan will regulate them according to the a model similar to that the Securities and Exchange Commission model uses for corporate stock offerings.

- Under this model, plans will be held legally responsible for fully and accurately disclosing all information about the plan to consumers. Plans that do not meet this requirement will be held liable for that failure.

15. Why haven't you placed restrictions on the type of utilization review criteria plans can use?

a. A key tenet of quality management under health care reform is that standards of care be scientifically based. However, requiring a "Good Housekeeping Seal of

Approval" for every single review criterion would be unduly burdensome, both for health plans and the government, and would create unacceptable administrative costs.

b. Instead, plans will be required to disclose their utilization management protocols. The Federal government will also carry out a program to develop science-based standards and procedures for evaluating the clinical appropriateness of utilization management protocols and of the methods for applying them.

c. Purchasers, and consumer groups will then be able to use the standards and procedures in evaluating use of a particular protocol.

16. Strategies to control utilization are the chief mechanism that a plan has to compete in the reformed health care system. Requiring disclosure of these strategies essentially requires them to share trade secrets with competitors. How can you justify this requirement under managed competition?

a. Utilization management protocols are "rules" by which care delivery determinations are made. Consumers, practitioners and purchasers should be informed of the rules of the care delivery system.

b. These protocols have the potential to become powerful incentives for inappropriate underutilization of care. It is important for consumers and purchasers to have this information when they are choosing plans on the basis of quality.

c. Plans will compete on which of the publicly-available utilization management methods they use, and on how well they apply them.

Strengthening Existing QA Structures

17. What will the role of voluntary accreditation organizations be in this new system?

a. Participation in the voluntary accreditation process will be encouraged under health care reform for both health plans and facilities.

b. The Federal government will have authority to determine that the accreditation standards and processes used by a voluntary organization would provide reasonable assurance that the Conditions of Participation for health plans or the certification standards for a type of facility are met.

c. The requirement for Federal certification of plans accredited by approved organizations, and the requirement for Federal certification and State licensure of facilities accredited by approved organizations, would be waived.

18. My mother needs to find a nursing home. How will health care reform protect her?

a. Under health reform the requirements for nursing homes that participate in Medicare and Medicaid will apply to all nursing homes in the country.

- These standards were enacted under a 1987 Nursing Home Reform Law. Since implementation began in 1990, quality in nursing homes has measurably improved.

- For instance, the number of nursing home residents who are restrained physically or chemically has been cut nearly in half.

b. Under health reform, States will provide technical assistance to nursing homes and other health care facilities to help them meet the Federal standards and improve the quality of their care.

19. How can you ensure that consumers will be protected by national standards under a system of State flexibility?

a. The same quality standards and quality measurement system will apply to health care in all States, whether or not they receive waivers from some other requirements contained in health care reform. In addition, the Federal government will exercise general oversight over state quality assurance activities.

b. With respect to standards for health care facilities the Federal government will assess whether each State's standards are substantially equivalent to the strengthened essential Federal standards.

c. If and only if they are substantially equivalent -- a criterion that will be strictly applied -- will that State be exempted from the requirement for Federal certification of facilities within its borders.

V. POLITICAL CONSIDERATIONS

A. PROVIDER GROUPS **(See Tab B for materials on groups)**

1. We met with the American Medical Association (AMA), and received a number of policy papers from them.

2. **The AMA is likely to support** the following aspects of our proposal, according to AMA policy papers:

- **Disclosure of utilization review criteria.**
- **Reducing the burden on physicians from the Medicare Peer Review Organization program.**
- **Reducing the burden on physicians from the Clinical Laboratory Improvement Amendments of 1988.**

3. **The AMA is likely to offer qualified support for public release of physician-specific quality measures.** The AMA has said it is not opposed to such release, as long as:

- The data are primarily used for education of consumers and providers;
- Physician groups and individual physicians have the opportunity to review and comment on data releases prior to the release;
- All data released is severity-adjusted and collected from carefully-selected studies where it may be deemed accurate, reliable, and meaningful to physicians, consumers and purchasers.

4. **The AMA would support the following additional proposal related to the quality working group's efforts:**

- Creation of a national commission to review the multiple regulatory burdens on the health care system and physicians and recommend elimination of unnecessary, ineffective and overly costly rules and the coordination of other regulatory efforts.

5. **The AMA is likely to oppose** the following recommendation, based on its past actions:

- **Creation and operation by the government of the national credentialing databases** recommended for use as part of the Conditions of Participation for health plans. The AMA operates its own database containing credentialing information.

B. CONSUMER GROUPS

1. **We have met with the following consumer groups**, who are members of the Coalition on Consumer Protection and Quality in Health Care Reform:

- American Association of Retired Persons (AARP),
- Families USA
- Gerontological Society of America
- Medicare Advocacy Project
- National Committee to Preserve Social Security and Medicare
- National Council on the Aging
- National Senior Citizens Law Center
- National Citizens Coalition for Nursing Home Reform

And with the following other consumer groups:

- Consumers Union
- National Association of Protection and Advocacy Systems

We have also received position papers from the Coalition and some of its member groups and from the Working Group on Managed Competition, which includes some consumer groups and consists of advocates of a single-payer system.

2. **Consumer groups supported** these aspects of our proposal:

- **Universal, nationwide application of the uniform quality standards** and methods of assuring quality.

- Publication of **comparative quality information** on plans, facilities, practitioners and treatments.

- **A quality oversight organization** that:

  - Is independent.
  - Reviews patterns of care
  - Conducts a consumer survey.

- A set of **minimum standards for health plans**, including:

  - Requirements for broad disclosure of information
  - A process for appealing decisions to deny or terminate treatment.
  - A formal grievance process
  - Disclosure of utilization management protocols

- **An ombudsman program.**

- Retention of the PRO program.

3. **Individual consumer groups also supported the following aspects of our proposal:**

   - AARP supports a continuous quality improvement approach to quality assurance, as long as that approach is backed-up with enforcement authority.

   - **The National Citizens Coalition supported retention in full of the 1987 Nursing Home Reform Law.**

4. **Consumer groups favored the following other proposals:**

   - Routine review of individual cases of care by the external quality oversight agency.

   - Governmental authority to act promptly in response to poor quality of care with a full range of sanctions. [These issues were considered by a working group on enforcement.]

   - Either heavy representation of consumers on a health plan board, or a separate consumer board to review utilization management decisions.

5. **Consumer groups are likely to be concerned about:**

   - Our recommendation to **change certification standards for health care facilities** other than nursing homes and to provide incentives for states to revise their licensure standards.

C. MANAGED CARE INDUSTRY AND COLLABORATING BUSINESS GROUPS

1. We met with:

- Managed Health Care Association
- Aetna Health Plans
- Prudential Insurance
- Xerox Corp.

We received position documents and other information from some of these and from:

- A group of 30 major managed health care plans, managed care organizations, businesses and consumer groups.
- American Managed Care and Review Association (AMCRA)
- Harvard Community Health Plan

2. In various communities and nationwide, the managed care industry has joined with groups of medium-to-large corporations in coalitions to develop database and quality measure and provide comparative quality information to purchasers.

3. **The managed care industry and its collaborating businesses strongly supports** our recommendation for:

- **A system of comparative quality information,** including a common set of performance measures, and a "report card" that would provide comparable information on quality.

  Note: These groups are working to develop their own quality measures and report cards, which they hope will be nationally adopted.

4. **Managed care-business coalitions are likely to support:**

- A set of minimum standards for health plans, compliance with which may be assessed by private, voluntary **accreditation** organizations.

These groups have been working closely with the National Committee for Quality Assurance, which was formed by the managed care industry and accredits HMOs.

5. **AMCRA opposes**, and much of the health insurance and managed care industry can also be expected to oppose, our recommendation for:

- **Public disclosure of utilization management protocols,** including utilization review criteria.

D. ACCREDITATION GROUPS

1. We met with the following groups that set standards for segments of the health care industry and assess compliance with those standards.

- Joint Commission on Accreditation of Healthcare Organizations (JCAHO), which accredits hospitals, home health agencies, and other facilities.

- National Committee for Quality Assurance (NCQA) which accredits HMOs.

We also received information from the following other accreditation organizations:

- American Accreditation Program Inc., which accredits preferred provider organizations (PPOs)

- The Community Health Accreditation Program (CHAP), which accredits home health agencies.

2. Accreditation groups will support our recommendations to:

- **Set minimum standards** for licensure and certification of facilities and Conditions of Participation for health plans, and

- **Allow facilities and health plans to demonstrate that they meet those standards through accreditation** by approved private groups.

3. JCAHO, NCQA and CHAP support our recommendations for:

- Development of systems for **quality measurement**

- Dissemination of **comparative quality information** based on the measures.

- A strong focus on **quality improvement.**

E. QUALITY EXPERTS

1. We met with the following individuals, each of whom has considerable expertise on health care quality issues:

- Don Berwick, Institute for Healthcare Improvement
- David Blumenthal, Massachusetts General Hospital
- R. Heather Palmer, Harvard School of Public Health
- Ernest Sessa, Pennsylvania Health Care Cost Commission
- John Ware, New England Medical Center
- Mark Chassin, New York State Health Commissioner
- Brent James, Intermountain Health Care, Utah
- Susan Horn, Intermountain Health Care, Utah

We also had contact with a large number of other experts on quality either by telephone or through the audits process.

2. In general, the **quality experts supported** our recommendations for:

- **A focus on quality improvement**, including:

  - Provision of **technical assistance** to plans, providers and practitioners.
  - Separating technical assistance from regulation.
  - Giving State technical assistance programs flexibility.
  - Requiring plans to demonstrate quality improvement

- Focusing consumer protection efforts on vulnerable populations, especially during the transition

- **Developing valid measures** of various aspects of quality, and feeding their performance on these measures back to plans and providers.

- Uniform national standards for plans and facilities, that are based on performance.

- Disclosure of utilization review criteria.

- Targeted **effectiveness research** and technology assessment.

3. Some of the quality experts were concerned about our recommendation for:

- Publishing a "report card" containing comparative quality information public, on the grounds that this could be viewed as punitive and could interfere with

plans' and providers' cooperative, internal efforts toward quality improvement.

Other quality experts strongly supported this recommendation.

4. Various quality experts made the following additional suggestions:

- That the health care improvement goals of the quality program be clearly stated, and that reduction in the Nation's burden of illness be a central goal.

- That competing plans and providers need to work together for quality improvement, and that antitrust laws and other barriers to this collaboration should be removed.

- Creation of a national quality commission akin to the Physician Payment Review Commission

- Presentation of awards to plans and providers that achieve quality improvement or participate in quality improvement efforts.

F. CONGRESSIONAL CONCERNS

1. Few Congressional health reform bills have addressed quality issues in a comprehensive manner.

- The Cooper bill H.R. 102nd Congress, adopted the recommendations of the Jackson Hole Group for publication of comparative quality measures to support purchaser and consumer choice.

2. Members of Congress are likely to support the following recommendations:

- Sen. David Durenberger, R-Minn., supports a "report card" to make the health care system accountable for its performance and to support consumer choice. [See United HealthCare report card press release]

3. Some members of Congress are likely to be concerned about our proposals to modify current Federal quality activities.

- House Energy and Commerce Committee Chairman John **Dingell**, D-Mich., and other Congressional sponsors of the 1988 Clinical Laboratory Improvement Amendments **(CLIA)** legislation, are likely to strongly oppose any changes to that law.

- A number of members of Congress, including Senators Jay **Rockefeller**, D-W.Va. and David **Durenberger**, R-Minn., have expressed concern -- though not necessarily opposition -- to Medicare's new direction for the **PRO program**, and believe it is being implemented too fast.

G. MEDICARE PEER REVIEW ORGANIZATIONS

1. We received position papers from representatives of Medicare Peer Review Organizations (PROs), including:

- American Medical Peer Review Association
- Michigan Peer Review Organization

2. These papers essentially called for the **expansion of the PRO program** to be the quality assurance mechanism for the entire health care system.

3. PROs are not likely to favor the quality working group's position, which is that PROs are free to compete to contract with States to carry out all or part of State quality programs.

4. The **PROs are likely to oppose** the quality working group's **recommendations to amend the PRO legislation** to be more consistent with health care reform, and with Medicare's new direction for the PRO program.

VI. Appendix

Tab 1

Quality Working Group Proposal

Tab 2