



Ensuring Fairness in Health Care Coverage Decisions

A consensus report on the ethical design and administration of health care benefits packages



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The **Ethical** Force Program™

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Disclaimer

The views expressed in this report represent a consensus of the members of the Ethical Force Program™ Oversight Body; they do not necessarily reflect the positions of the organizations with which members are affiliated. Individual participation on the Ethical Force Expert Advisory Panel on Benefits Determinations does not imply endorsement or approval of the final report.

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Executive Summary

The Ethical Force Program™ is a collaborative process that creates performance measures for domains of health care ethics that can be applied to all participants in health care delivery.

Ethical Force is based on the understanding that all participants in the health care delivery system share certain core ethical obligations by virtue of their participation in this unique enterprise. Although ethical standards may legitimately vary across business, public health, personal, and professional relations, recognizing a core set of *shared* ethical expectations is critical in health care environments. In addition, valid, reliable, and feasible performance measures regarding these ethical expectations would be useful for health care quality assurance and improvement.

This report addresses the ethical issue of improving the fairness of health care coverage decisions, including both the design and administration of health benefits packages. The Ethical Force Oversight Body—consisting of leaders from health care delivery organizations, professional and patient organizations, government, accrediting bodies, unions, and the business community—decided to address coverage decisions following a process of deliberation as to which ethical issues in health care might best be addressed through a consensus-building process. Recent evidence suggests that patients and physicians too often perceive that coverage decisions are made in unfair ways or by using inappropriate criteria. This perceived unfairness is compromising trust in the health care system. While difficult coverage decisions must be made, trust in the legitimacy of these decisions is required for the health care system to be most effective and valuable.

Developing realistic mechanisms to promote trust in health care organizations by fostering and demonstrating fairness in coverage decisions would provide value to all participants in the health care system. This report presents a framework for doing precisely that.

The report was created using a rigorous process for consensus building, including substantial input from a national Expert Advisory Panel and multiple rounds of formal and informal Oversight Body review. A draft of the report and a comment form have been posted on the Ethical Force web site www.ethicalforce.org for the past year, and more than 800 leaders from throughout the health care system were mailed copies of the early draft with an invitation to offer comments and suggestions.

This report contains more than broad ethical principles that should be taken into consideration when an organization designs or administers a health benefits package. It presents an action agenda. The Ethical Force Program™ ultimately aims to foster the development of performance measures for ethics in health care. The report presents five *content areas* for performance measurement, followed by a series of *measurable expectations* within each content area. These are concrete recommendations for measurable actions that can be taken by specific organizations to demonstrate that attention is being given to each of the five content areas with regard to both the design and administration of health benefits packages.

Future stages of development for this project may include the creation and field-testing of organizational performance measures based on the listed expectations, depending on the demand for these measures. Even without such measures, however, this consensus framework provides a model for the design and administration of health care benefits packages, which should be useful to a wide variety of organizations that are concerned with ensuring the fairness and legitimacy of these processes in the eyes of patients.

The five content areas, and a summary of the measurable expectations recommended within each area, are listed below.

Organizational processes for designing and administering health benefits should be:

- Transparent
- Participatory
- Equitable and Consistent
- Sensitive to Value
- Compassionate

Area 1. Transparent. *The processes for designing and administering health benefits should be fully transparent to those affected by these processes.*

The need for transparency affects all subsequent content areas. Transparency is central to accountability, and it requires active attention beyond simply making documents available upon request. Organizations making coverage decisions should provide enrollees/beneficiaries with:

- A copy of a statement of the goals of the coverage;
- A clear definition of who is included in the covered population;
- The types of rationales that may be used in making coverage decisions.

Organizations should also ensure that:

- These materials are understandable;
- A contact person, such as an ombudsman, is available when questions or concerns arise;
- A written description of the rationale(s) that justify coverage denial is provided to the individual to whom coverage is being denied.

Area 2. Participatory. *Organizations should purposefully and meaningfully involve all stakeholders in creating and overseeing the processes for designing and administering health benefits.*

Organizations can ensure and demonstrate the meaningful participation of all stakeholders by:

- Including relevant stakeholders in decision-making bodies;
- Actively soliciting input from all stakeholders;
- Using the information gathered from stakeholders in decision-making.

Some participants in the health care system have special responsibilities to encourage the participation of others. In particular:

- Practitioners should create a clinical practice environment that fosters shared decision-making about treatments and that empowers patients in managing their health;
- Benefits consultants and insurance brokers should take into account the needs, values, and priorities of enrollees/beneficiaries as well as purchasers and health plans when formulating benefit design recommendations.

Area 3. Equitable and Consistent. *Processes for designing and administering health benefits should result in similar decisions under similar circumstances.*

Attention to equity ensures the recognition of meaningful similarities and differences between illnesses and conditions, while attention to consistency ensures the uniform application of coverage rules. Organizations can attend to equity and consistency by making coverage criteria clear, easy to interpret, and based on reasonable and non-discriminatory rationales. Among other steps in this area, we recommend that:

- Organizations adopt written criteria for benefits decision-making;
- Organizations that adjudicate coverage appeals maintain written records of these decisions, including the rationales for the decisions;
- Written records be consulted when similar situations arise subsequently.

Other recommendations are to ensure the independence of appeals processes and to reflect evolving legal and regulatory standards in this regard.

Area 4. Sensitive to Value. *Processes for designing and administering health benefits should take into account the net health outcomes of services or technologies under consideration and the resources required to achieve these outcomes.*

Clinical value to beneficiaries should be the foremost concern in designing and administering health benefits. However, there is a limited, but sometimes important, role for cost-effectiveness analysis in assessing the value provided by potential services. Among other steps, we recommend that organizations:

- Assess the benefits, harms, and risks of proposed services using the best available clinical and scientific data;
- Employ cost-effectiveness analysis (CEA) using standardized methods when comparing two treatments or tests that are expected to have similar clinical efficacy but substantially different costs. If one treatment option is substantially more effective than available alternatives, especially for serious conditions, CEA is unlikely to yield information that will alter decision-making and generally is not warranted;
- Give priority to the most cost-effective service or treatment option when more than one similarly effective alternative is available. Exceptions should be made for individuals for whom alternatives would provide unique benefits or who face unique harms from the preferred option;
- Recognize that CEA results and methodologies pose important ethical and practical concerns and that factors in addition to aggregate costs and benefits must be considered when making coverage decisions for individuals.

Area 5. Compassionate. *The design and administration of health benefits should be flexible, responsive to individual values and priorities, and attentive to the most vulnerable individuals and those with critical needs.*

Compassion and flexibility in making coverage decisions are important in order to respect individual values and circumstances, to ensure the social acceptability of coverage decisions, and to maintain the integrity of health insurance. Flexibility and consistency (Area 3) can conflict, however. To avoid such conflicts, flexibility should be exercised using:

- Consistent criteria
- A uniform process

Benefits packages can be responsive to different individual values and priorities by:

- Providing meaningful choices for supplemental coverage options.

Compassion for those with special needs may be expressed through:

- Making appeals processes fair and timely;
- Fostering appropriate advocacy from professionals.

These five content areas and expectations are derived from numerous other sources and rest on broadly-accepted community norms for ethical behavior and fairness in decision-making contexts (see Appendix D, Review of Existing Norms and Standards). Many organizations that design and administer health benefits already use these principles and live up to many of the listed expectations. But few organizations today can demonstrate that they attend well to all of these issues—and patient trust in the health care system suffers as a result. Although each of these content areas is very important, each should be balanced by attention to the others. Moreover, it takes only a few organizations to disrupt the entire system by eschewing their ethical obligations related to these issues. This report, coupled with the prospect of measuring whether organizations are meeting the listed expectations, should provide fresh impetus for organizations throughout the health care system to develop a level playing field, ensure the fairness of coverage decisions, promote trust in the health care system, and improve the health and well-being of the population.

Section I

Introduction and Scope of the Report

Introduction

For the first time, the Ethical Force Program™ brings together high-level representatives of practitioners, patients, health plans, government, unions, employers, and other organizations to develop consensus and plans of action to address important ethical issues in health care. This report presents a groundbreaking attempt to lay out a framework addressing perhaps the most contentious set of issues facing the health care system today: the processes by which coverage decisions are made and the criteria that should be used in making these decisions. The result of intense meetings and a rigorous process lasting more than 2 years, this report describes the stakeholders' consensus on an ethical framework for designing and administering health benefits, including specific steps to improve and ensure the fairness of coverage decisions. Health care coverage decisions are complex and involve many considerations. *This framework is based on ethical considerations. It does not address every outstanding issue related to health care resource allocation.* It does, however, provide tangible and measurable ways to increase trust in the health system by enhancing and ensuring the equitable design and administration of health benefits.

Background: The Ethical Force Program™

Ethics in health care are important because caring for the ill is a moral enterprise that requires the trust of patients, and is also a large and diverse business.¹ Today, each participant in health care delivery can be strongly affected by the ethical standards of many other participants. In contemporary health care, business, public health, medical, personal, and professional ethical standards are in force concurrently, yet may be in conflict.¹⁻⁵ Everyone can be affected by ethical conflicts in the health care system, but patients are most at risk. Trust in the health care system relies on every stakeholder being accountable to others in the health care community in one way or another.

The Ethical Force Program™ believes that balancing various ethical standards to promote trust requires the creation of a “mutual and multilateral web of accountability for ethics” among all participants in health care.⁶ For such accountability to succeed, it is necessary to identify and agree upon a *shared* set of fundamental ethical expectations. Ethical Force is a collaborative effort among numerous participants in the health care delivery system to develop those shared expectations. Further, Ethical Force aims to create

expectations that can be feasibly met or exceeded as well as validly and reliably measured. Through its consensus building process, Ethical Force hopes to increase fairness through accountability and improve health care by fostering the ethical behavior of all participants.⁷

Ethical Force hopes eventually to foster performance measurement in relation to ethical standards. Ethical Force was thus organized as, and uses the terminology of, a performance measurement program. Ethical Force uses a stepwise process toward performance measure development, which begins by identifying and defining a specific *domain of ethics* that needs to be addressed by participants throughout the health care system. Then, a framework for assessing the domain is created by dividing the domain into relevant *content areas*, which are aspects of the domain that should be considered for an ethical assessment. Next, within each content area, specific *measurable expectations* of performance are described. Both the content areas and the measurable expectations within them are delineated using a rigorous consensus process that involves the Oversight Body for Ethical Force, a national Expert Advisory Panel appointed by the Oversight Body (see Appendix A), and multiple outside reviewers. In this instance, early versions of this report were mailed to more than 800 leaders throughout the health care system for review. Through this process, Ethical Force hopes to ensure that the framework and expectations in this report are important, feasible to address, and, unless specifically noted, applicable to all organizations involved in health care benefits design and administration.

Future stages of development for this project may include the creation and field testing of organizational performance measures based on the listed expectations, depending on the demand for these measures. Even without such measures, however, it is hoped that this consensus framework will provide a model for the evolution of health care coverage decisions in a wide variety of organizations to enhance and ensure fairness, legitimacy, and trust in the eyes of patients.

In separate work, Ethical Force developed a unique methodology to help delineate and select core domains of health care ethics for assessment.^{8,9} The first ethical domain addressed by Ethical Force focused on protecting the privacy and confidentiality of identifiable health care information.^{10,11} The consensus report on this issue was released in January 2001, and performance measures in this domain are now in field testing. (For more information, see www.ethicalforce.org).¹⁰ This report is thus the second in a planned series of consensus reports addressing a variety of domains of health care ethics.

Defining Terms: Access to Care, Benefits Design, and Coverage Administration

Resource allocation systems in health care are complex, and coverage decisions are made at multiple levels. In particular, questions about the fairness of coverage decisions tend to arise in three basic areas: access to care, benefits design, and benefits administration.

Access to health care is the degree to which individuals and populations can and do obtain health care despite various barriers, including financial (such as lack of insurance), cultural (such as language or trust barriers), and geographic (such as long distances or other difficulties faced to reach health care facilities).

Benefits design is the decision-making process that determines what assortment of health care services will be included in an insurance package, including issues regarding copayments, deductibles, and provider reimbursement.

Benefits administration is the decision-making process that determines the insurance coverage of specific services for specific individuals within the scope and limitations of the benefits design, including individualized coverage decisions and the adjudication of appeals.

For example, state Medicaid programs may address *access* in part by providing insurance coverage to certain categories of citizens, such as low-income women with children. The Medicaid benefits package might then be *designed* so that it covers the costs of “medically necessary inpatient care” for this covered population of patients. *Administration* of this benefit entails establishing processes to determine whether specific proposed inpatient services are “medically necessary” for one or more covered persons.

Scope of this Report

This report addresses only two of these three areas: benefits design and administration. While some issues of access, such as cultural and geographic barriers for individuals with insurance coverage, are touched upon in this report, the broader issue of lack of access to insurance coverage—that is, the problem of the uninsured—poses unique and important ethical and social challenges. The Oversight Body ultimately decided that these challenges warranted separate consideration. Indeed, some members of the Oversight Body argued for a focus solely on benefits administration, setting aside benefits design because it too poses complex problems that reach beyond ethical considerations. However, the consensus of the Oversight Body was to address both benefits design and administration, contentious though the former may be. These decisions—to set aside access and to address benefits design issues—were not easy for the Oversight

Body to make, and the competing arguments heard are summarized in Appendix C.

Coverage Decisions Are Complex but Important

The integrity and fairness of the systems through which health benefits are designed and administered comprise an important, though underexplored, domain of health care ethics.¹²⁻¹⁸ Benefits package design and administration are central to health care delivery, and numerous parties are involved. Purchasers of various sorts—insurance brokers, unions, health care financing and delivery organizations, practitioners, and patients—all play important roles. Although each participant plays a special role, the roles are often blurred.

Employers, unions, government, and other purchasers generally decide what sorts of benefits packages to offer—that is, they design benefits packages for beneficiaries. Health plans and clinicians are charged with administering these packages—that is, making coverage decisions for individuals. However, sometimes purchasers are involved in administration issues, especially when self-insured and assuming both payment and management functions. And health plans frequently negotiate with purchasers, brokers, unions, and others about benefits package design, which they must then administer.

On top of these overlapping responsibilities, each party in the health care system may recognize different competing demands on available resources as well as differing ethical standards as to what are considered “good” decisions. Valid distinctions often exist between professional ethics, business ethics, public health ethics, and personal ethics.^{1,2,4} Moreover, some have debated whether ethical considerations play any role at all in current benefits design processes, which must attend to costs and other issues (see Appendix C). Given the varying standards and priorities (ethical and otherwise) within organizations, deciding how to apply different criteria when designing and administering health benefits packages is one of the most complex and potentially divisive challenges health care leaders now face.¹⁴

Facing these challenges has caused tension between important stakeholders in the health care system. All too often, patients and practitioners appear to reject the fairness or legitimacy of coverage decisions, evincing mistrust in the health care system. Recent research demonstrates that both physicians and patients sometimes feel justified in “gaming” insurance company coverage decisions.¹⁹⁻²¹ Other research shows that coverage decisions vary widely and sometimes inexplicably.²² Trust in health care institutions is under stress^{23,24} and may be affected by coverage decisions.²⁵ Many patients report that they believe their health plan is more concerned with saving money than

with maintaining their health.²⁶ Further, amidst these rising tensions, there is a risk that some groups are becoming scapegoats for difficult decisions while others may be escaping scrutiny. For instance, the important role of purchasers in designing benefits packages may not be recognized when insurers and practitioners are seen to implement benefits restrictions. Important trade-offs between cost and coverage may also be opaque to consumers/patients who ultimately pay for benefits packages but are rarely involved in designing them.

Despite the challenges discussed above, coverage decisions must be made. And, because health care is a service that is of particular social importance,^{13,27} it is critical that these decisions be made as fairly as possible.

The Value of Following the Recommendations of the Consensus Report

The Ethical Force Program™ believes that close attention to ethical norms in health care has intrinsic value for organizations and individuals, independent of potential financial or other benefits that may accrue. But we also recognize that limited resources in health care must be used to address many important concerns. Following the recommendations in this report will require resources and therefore will need to be justified. Fortunately, meaningful short- and long-term organizational benefits are likely to result from following the recommendations laid out in this report. A full account of the “business case” for attention to ethics in coverage decisions, as well as barriers to realizing progress on this front,^{28,29} would require an additional report, but we have summarized a few key considerations here.

In general, many health care organizations are paying increasingly close attention to ethics and what is necessary to build an organizational culture of integrity, reliability and trustworthiness.⁴ This consensus report will help to foster these burgeoning initiatives. A primary goal for many organizations is to create a culture and reputation built on openness, care, and respect for individuals and their families. These organizations understand that earning trust and sustaining loyalty are key to forging productive relationships and long-term success.^{30,31} In some instances, organizations are also financially rewarded through increased capital investment on the part of investors who monitor the ethical behavior of organizations.^{32,33} Approximately \$2.3 trillion, about 13% of all professionally managed investments in the United States, is invested using “social criteria,” such as employee relations and the types of benefits offered (personal communication, Carsten Henningsen, Chairman, Progressive Investment Management, May 28, 2003).

In addition, following the recommendations in this report will result in specific benefits for some of the major stakeholders in health care. For *health plans*, making

coverage decisions can be emotionally charged. Turnover among enrollees may be related to coverage denials that are perceived as irrational or unfair (personal communication, Chris Smith Ritter, Project Officer, Medicare CAHPS Disenrollment Surveys, May 29, 2003).²⁵ Many health plans will immediately recognize the business value of being able to demonstrate careful attention to organizational attitudes and policies that reflect fairness and ethical consistency when making coverage decisions. For *purchasers*, the cost associated with changing health plans can be enormous. Focus groups conducted by the Ethical Force Program™ in preparation for this report suggest that many employers do not prospectively assess whether health plans have systems in place to ensure that coverage decisions are made fairly in the eyes of their employees.³⁴ Instead, many employers respond aggressively, but retrospectively, when employees complain about coverage denials. Employers, as health plan purchasers, may find the opportunity of having a proactive method for evaluating coverage decision-making processes especially appealing if it can avoid the need for later appeals, unpleasant interactions with plan administrators, or benefits package changes. Meanwhile, for *patients*, knowing that coverage decisions will be unbiased and fair is integral to building a strong sense of trust and justice in their health care system.^{24,25,35,36} Studies have shown that patients with greater levels of trust are more likely to adhere to treatment recommendations, less likely to switch providers, more likely to participate in their own care, and have better health outcomes.³⁷⁻⁴¹ In this regard, organizations that represent enrollees/beneficiaries, such as labor unions, might also find the report to be of use in negotiations with employers over the value of providing fair and equitable health care coverage.

Health care practitioners will benefit if organizations follow the recommendations in this report because they encourage fair and efficient coverage decisions, which should result in fair and efficient payment for providing covered care. Evolving relations between physicians and managed care organizations are being built on initiatives to foster the values of openness, clarity, and participation, all of which are promoted in this report.^{42,43} In addition, the recommendations aim to create a more widespread understanding about how to achieve thoughtful and prudent use of limited resources. Such an understanding might be expected to encourage more appropriate coverage and utilization of services, including preventive care and management of long-term illnesses, which are known to improve health outcomes and often reduce costs.

Finally, the argument for fostering ethical values and accountability at every level of health benefits coverage decisions must also include consideration of the potential costs associated with failing to follow this report’s recommendations. For instance, there have been numerous news reports and even court cases—involving purchasers,

providers, and practitioners—where decision-makers have been held accountable for coverage decisions that could not be substantiated and/or were perceived by the public to be unfair. Demonstrated attention to principled behavior in coverage decisions may mitigate such adverse exposure and the resulting losses of economic and social stature that can ensue.

Section II

Methods

The Stages of the Ethical Force Process

The Ethical Force Program™ has developed a three-stage framework for developing performance measures in domains of ethics, including some of the most complex and divisive issues in health care (Figure 1).¹ This report is the result of the first stage, where the Ethical Force Oversight Body (1) selected a particular domain of ethics for performance measures development, (2) worked in an iterative process to develop a framework and expectations for assessing the domain, and (3) presents its consensus on some concrete steps that organizations can take to improve performance, (Figure 2).

A national Expert Advisory Panel on Coverage Decisions in Health Care was appointed by the Oversight Body near the beginning of this process (Appendix A). Its first charge was to review existing ethical norms and performance standards for the selected domain. (For a summary of this review, see Appendix D.) The review was then used by the panel to recommend how to identify reasonable content

areas and provide a framework for assessment. These content areas were carefully reviewed, revised, and approved by the Oversight Body, which considered whether (1) any relevant considerations were being ignored and (2) all the areas being addressed were important. This review process included the use of numerical rating scales (from 1 to 10) to assess each content area on its overall importance and relevance specifically to the issue of coverage decisions. Areas with marginal scores (mean < 7) were reassessed, revised, or eliminated during face-to-face meetings of the Oversight Body. This formal review process was designed to ensure the content validity of the overall performance measurement framework.⁴⁴

The five content areas approved by the Oversight Body provided a working framework for the development of measurable expectations for performance. After approval of the content areas by the Ethical Force Oversight Body, the Expert Advisory Panel identified many potentially measurable expectations within each content area. These are specific expectations for action in each area that can be measurable within organizations in a valid, reliable, and feasible way.

For example, Content Area 1 is entitled, “Transparent.” Within this area, a set of measurable expectations lists specific actions, or steps, that organizations can take to ensure that the processes used in benefits design and administration are readily visible to those affected by coverage decisions. One such measurable expectation is that organizations should provide “an organizational contact person or office to whom enrollees/beneficiaries may turn with questions or concerns about their health benefits.” (recommendation 1.2b) Providing such a contact person is a reasonable expectation (many organizations

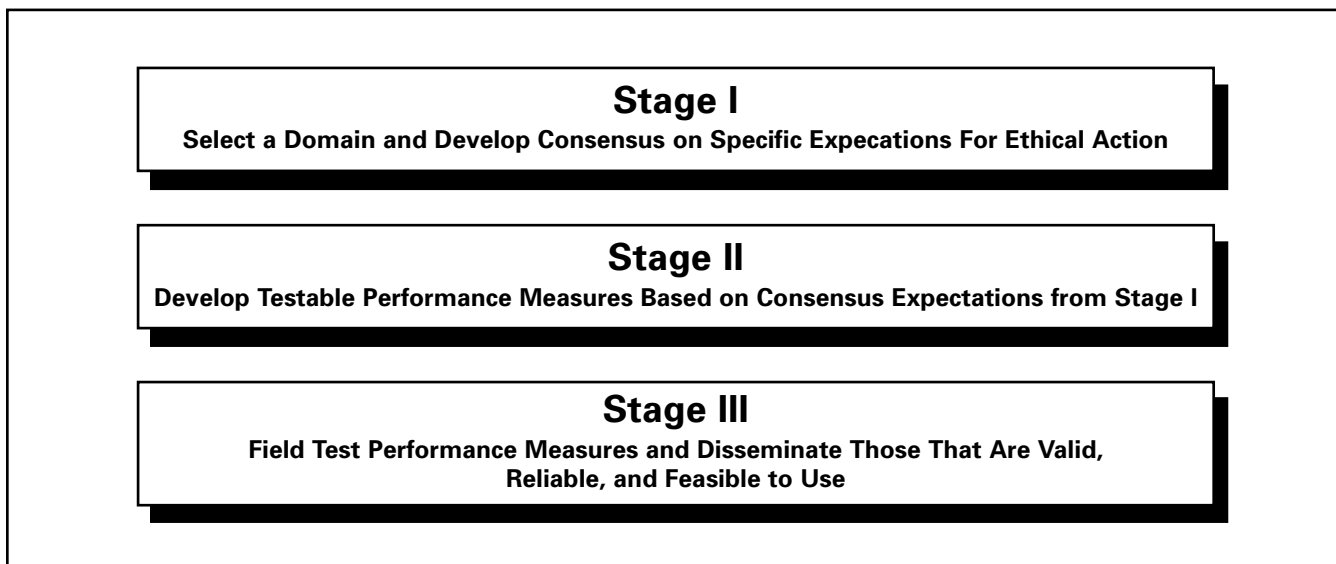


Figure 1

Development of the Consensus Report

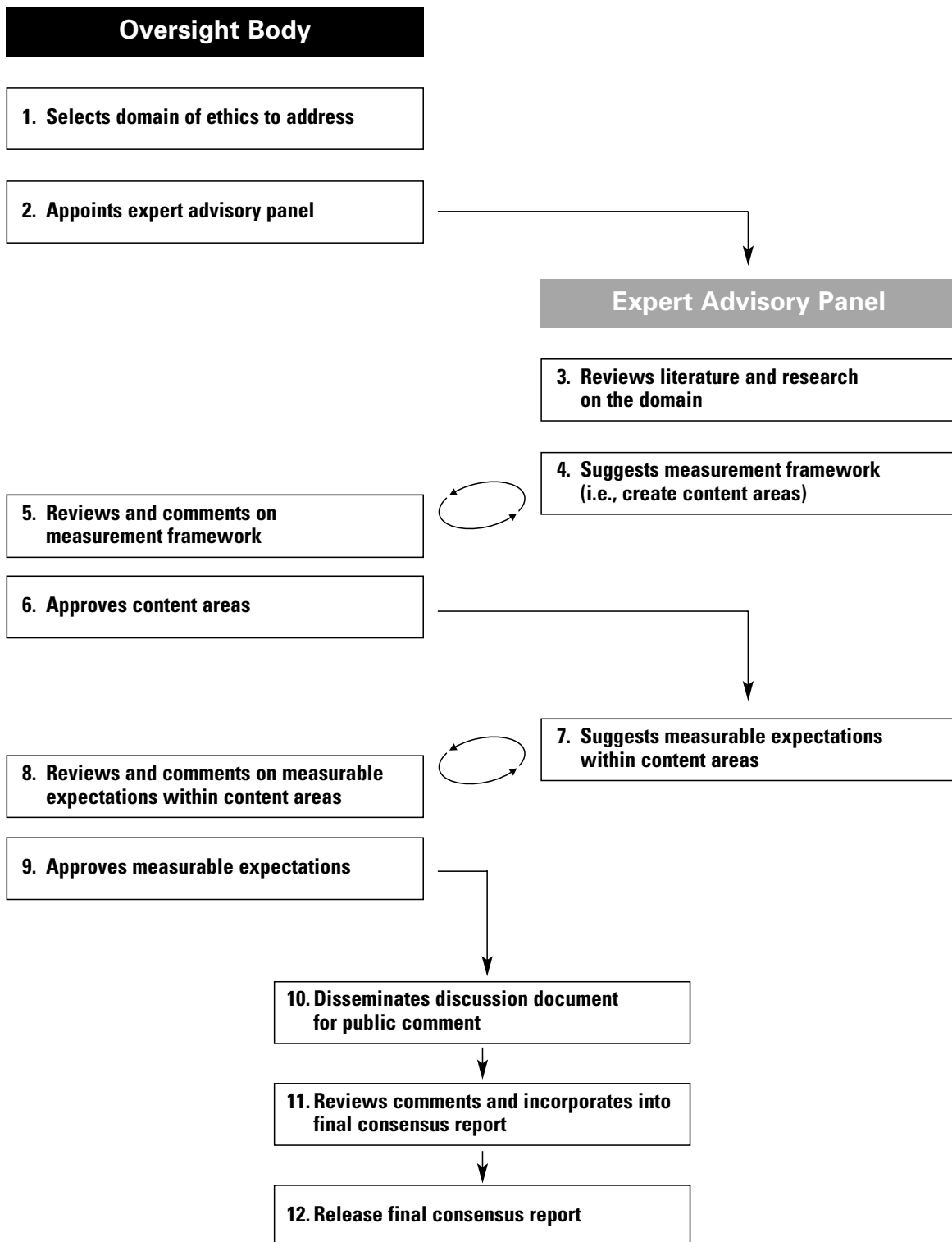


Figure 2

have an ombudsman, for example), and whether or not an organization does so can be measured in valid, reliable, and feasible ways.

The Expert Advisory Panel and the Ethical Force Oversight Body systematically reviewed each proposed expectation for its (1) overall importance, (2) feasibility of implementation, and (3) potential for measurement. In this review process, each Oversight Body member gave each item numeric grades (from 1 to 10) for its importance, feasibility, and measurability. Those items receiving marginal scores (mean score < 7) in any of these three categories were reviewed and revised or eliminated.

This formal grading process was repeated three times over a period of 2 years, with extensive revisions between each iteration, in order to attain an acceptable consensus among Oversight Body members. During this process, the Expert Advisory Panel met in-person five times and conducted numerous conference calls and e-mail communications. The Oversight Body met in person four times, each time making substantive recommendations for revisions. Finally, in spring 2002, a draft of this report was mailed to more than 800 health care leaders nationwide, soliciting feedback and comments. The report was then revised and reviewed again by the Oversight Body (and in more detail by the Oversight Body writing group) to address as many of these comments as possible.

Like the previously issued Ethical Force report on privacy and confidentiality,¹⁰ this report is the end result of a rigorous consensus-building process both within and outside the Oversight Body. It establishes a framework and recommendations to guide organizational action. It does not, however, present a set of performance measures. In future stages, the measurable expectations listed in this consensus report may be used to create performance measures, depending on the demand for such measures (Figure 1). Typically, performance measurement tools include survey items (most often for enrollees/beneficiaries or practitioner surveys), site review criteria, policy review criteria, or other document audits.^{1, 10, 44, 45}

Performance measures based on Ethical Force consensus reports are created in an open and collaborative process, working closely with experts who develop and implement performance measures. Proposed performance measures undergo field testing to ensure that they are valid, reliable, and feasible. Based on field testing, implementation and interpretation guides are created to facilitate adopting the measures for self-assessment, peer review, accreditation, report card projects, and other quality assessment and improvement projects.¹

Section III

Measuring the Quality of Benefits Design and Administration Processes

One thing that distinguishes the Ethical Force Program™ approach from other current ethical frameworks is Ethical Force's interest in moving beyond theorizing about ethical standards for benefits design and administration to promoting the development of valid, reliable, and feasible performance measures for attaining shared ethical expectations.¹

Measuring "Ethics Quality"

Today, public demands, legislation, technological advances, and financial pressures have generated considerable interest in the development of tools to measure the quality of health care. Though most health care quality measures address customer service (such as waiting times) or technical competence (such as operative outcomes or frequency of using screening tests), Ethical Force believes that an organization's ethical culture is also very important to health care quality; that is, *measuring whether organizations meet or exceed ethical expectations is key to understanding health care quality*.^{1, 7, 46}

Measuring an organization's ethical culture regarding coverage decisions is especially difficult because numerous parties hold important stakes in these decisions. As noted in Section I, each party may have different ethical standards based on business, professional, public health, or personal ethics, and these standards may influence their actions when making coverage decisions. Therefore, as with many important areas of health care quality, there is no uniform "gold standard" for measuring the quality of coverage decisions.

In areas of performance measurement where no gold standard exists, quality measures instead must focus on measuring (1) adherence to *basic norms*, (2) use of *procedures* to facilitate quality assurance and improvement and to ensure appropriate attention to important and complex issues, and (3) organizational *progress* toward goals that are recognized as aspirational.¹ The Ethical Force effort in this domain utilized a similar process. First, as noted in Section II and detailed in Appendix D, this effort began with a review of the literature on how coverage decisions are, or should be, made. Based on this review, consensus around several themes suggested that some widely-held basic norms exist. These norms form the core of many of the expectations listed in this document.

Second, process measures and procedural issues are particularly important in this domain because measuring performance based on substantive outcomes poses special problems. Specifically, so many variables are involved in making coverage decisions that it is highly unlikely that consensus could be achieved on specific desirable outcomes—that is, a detailed listing of services that should always, or never, be covered. Indeed, it is expected that coverage decisions will vary according to changing needs, priorities, and resources. Therefore, organizations responsible for making coverage decisions must strive to ensure that they follow ethical processes in addressing these complex decisions.

Finally, some aspirational goals are also noted. Within the measurable expectations, the aspirational goals are relatively few because, although they are often quite important, reviewers tend to give them low grades for feasibility of implementation and measurement. Thus, aspirational statements often appear in the descriptions of the content areas, but only rarely appear in the specific expectations listed within each content area.

A Framework for Performance Measurement

Building from our review of existing theories and policies, (see Appendix D) Ethical Force proposes five general content areas that are directly related to the fairness of health benefits design and administration. In short, health care coverage decisions should be (1) transparent, (2) participatory, (3) equitable and consistent, (4) sensitive to value, and (5) compassionate. Clearly, these five considerations are not exhaustive. Rather, they constitute what the Ethical Force Oversight Body has determined to be minimal for the assessment and improvement of fairness in these types of decisions. To improve fairness and ethical acceptability, all processes for designing and administering health benefits packages should incorporate attention to each and all of these content areas. (Exactly how much attention and how the content areas may interact is addressed below and will also be the subject of measure scaling and validation testing.)

Order of Attention: The five content areas are not listed in order of importance, but rather in the logical order in which they might be considered in decision-making processes. For example, the last content area calls for the entire process to be compassionate to all relevant stakeholders. This does not imply that compassion is less important than the preceding content areas, but rather that, as a final step in ensuring the legitimacy of the decision-making processes, it must apply to all the preceding issues.

Limitations of the Framework

At the outset, it is important to set realistic expectations for what this report can accomplish. First, no single set of performance expectations can guarantee high quality. This is perhaps especially true in domains of ethics. Organizations that intend to use adherence to ethical norms merely as window dressing will virtually always be able to do so, and it is possible that Ethical Force recommendations to improve fairness in benefits design processes might be skirted or “gamed” (see Appendix C). In this regard, it is important to recognize that no set of expectations or measures can provide an ironclad guarantee of truly ethical actions. The hope of Ethical Force is that organizations that attend to the recommendations listed will be more likely to act fairly and with integrity rather than less so.

Legal and Regulatory Limitations: In identifying the content areas and measurable expectations listed below, the Ethical Force Oversight Body recognizes the limits that may be placed on organizations with regard to benefits design and administration due to existing legal and other regulatory frameworks. For example, many health benefits are mandated by state or federal law, and appeals adjudication processes are becoming more standardized due to evolving legal and accreditation requirements. We note that, in many cases, these frameworks can facilitate fairness. (For example, evolving standards for adjudicating appeals are consistent with Ethical Force consensus recommendations.) But there may be other cases where regulations or mandates directly conflict with the ethical content areas listed in this report and hinder organizations from meeting legitimate ethical expectations. We are not aware of instances where the expectations we have articulated directly conflict with the law, but it is important to note that, if there are such cases, organizations and individuals should obey the law. Nevertheless, we concurrently recognize an obligation of health care professionals to seek changes to the law where such changes would improve health care.^{47, 48}

The Evolving Health System: Ethical Force also recognizes that the health care system will continue to evolve. For example, in 2002, some key organizations in health care included health plans, employers (acting as health plan purchasers), and the federal and state governments (acting as purchasers, regulators, and providers). Over time, these organizational entities may change. For instance the role of individuals may increase in selecting specific health benefits for the insurance coverage they wish to purchase. Ethical Force has worked to establish principles and recommendations that can guide coverage decisions regardless of who has the final say in making them.

Realistic Expectations: Finally, we note that not all of the participants in today's health care system are meeting the expectations we list. Indeed, this work would be irrelevant if they were. However, we suspect that some organizations do currently meet all of these expectations. And we know that there are many organizations today that are meeting or exceeding each particular expectation listed, which suggests that Ethical Force has set realistic targets. Nevertheless, some organizations—in particular small purchasers, such as small employers—may feel that it is impossible to live up to all of the expectations listed in this document. This might not be an indictment of these organizations or an indication that the recommendations in this report are wrong; rather, it may reflect a health care system that literally asks the impossible of some of its key participants.

The Five Content Areas

Processes for designing and administering health benefits should be:

- 1. Transparent.** The processes for designing and administering health benefits should be fully transparent to those affected by these processes.
- 2. Participatory.** Organizations should purposefully and meaningfully involve all stakeholders in creating and overseeing the processes for designing and administering health benefits.
- 3. Equitable and Consistent.** Processes for designing and administering health benefits should result in similar decisions under similar circumstances.
- 4. Sensitive to Value.** Processes for designing and administering health benefits should take into account the net health outcomes of services or technologies under consideration and the resources required to achieve these outcomes.
- 5. Compassionate.** The design and administration of health benefits should be flexible, responsive to individual values and priorities, and attentive to the most vulnerable individuals and those with critical needs.

Measurable Expectations for Each Content Area

Each content area is described below in more detail, with a brief explanation of the ethical foundations of the area. The explanation is followed by the benefits and limitations associated with attending to the content area in health benefits design and administration, as well as comments on how the various content areas fit together. A table for each content area then lists measurable expectations for organizations to help ensure that attention is being paid to that area. Within each table, expectations regarding

benefits design are listed first, followed by expectations regarding benefits administration. Some tables are further divided (if necessary) into those expectations that apply to all organizations making coverage decisions and any expectations that apply only to one or a few participants. Finally, each content area may have one or more Explanations and Exceptions points, which describe any special issues or potential pitfalls that may be encountered in working to achieve the expectations listed.

Content Area 1.

Transparent

The processes for designing and administering health benefits should be fully transparent to those affected by these processes.

All aspects of the processes for health benefits design and administration should be known, or at least knowable, to those directly affected by them, including those who are considering whether to submit themselves to the process (such as potentially new enrollees in medical practices and health plans or, in many cases today, potentially new employees/beneficiaries). Transparency regarding the results of benefits design and administration processes, how they work, and the rationales used are all important.

The ethical importance of transparency is derived from the importance of being honest and holding individuals and organizations accountable for their decisions. Increasingly, individuals are expected to accept coverage decisions because, as informed consumers, they have agreed to a specified benefits package and set of administrative procedures.⁴⁹ But, to ethically hold individuals accountable in this way, valid information about covered services, and how new services are evaluated for coverage, must be provided to the individuals before they are asked to make choices. Likewise, organizations—both purchasers and providers—can only be held accountable through the marketplace when consumers make choices based on sound and complete information.⁴⁵ Organizations also cannot be held accountable for appropriate stewardship over limited resources if all other stakeholders are not open and honest in communicating their own needs, values, and priorities.

Limitations

Despite the importance of transparency, it is inherently limited because it is not possible to convey all information to all people. The exact extent to which each aspect of a decision-making process must be made clear to all stakeholders may be controversial. How much of an organization's resources should be used to convey information about a new or revised benefits package,

for example, will vary depending on the scope and importance of the change. In general, it is much more important (and realistic) that enrollees be given information on how new services are evaluated for coverage (who is involved in the decisions, using what criteria, etc.), than it is for every enrollee to be actively informed each time a new service, drug, or technology, is approved for coverage.

Expectations

Transparency is closely related to all subsequent content areas and requires active attention. It is not sufficient merely to make documents available upon request. Because transparency affects all subsequent content areas, several of the expectations in Table 1 are reflected in later tables. Truly transparent processes should (1) seek out the participation of all stakeholders in equitable, fair, and consistent ways, (2) clarify how the special sensitivities of vulnerable and special needs individuals are incorporated into decisions, and (3) openly

acknowledge the role of health outcomes assessments in making coverage decisions.

Specifically, organizations involved in the design or administration of health benefits should provide enrollees/beneficiaries with a statement of the goals of the health benefit package, a clear definition of who is included in the covered population, and the types of rationales that are used in making coverage decisions. Organizations should ensure that these materials are understandable and should provide assistance in interpreting them as necessary. One step should be providing a specific contact person, such as an ombudsman, to be available when questions or concerns arise. Similarly, when individuals are directly affected by administrative decisions, such as during an appeals process, a written description of the rationale(s) that justify the decision should be provided. This will not only encourage an open and transparent process, but also promote equitable and consistent decisions.

Table 1

Expectations* of All Organizations Involved in Designing Covered Benefits**

- 1.1 The organization makes available written statements for beneficiaries/enrollees that, at minimum, include:
 - 1.1a A statement of the primary goals of the health benefits package;
 - 1.1b A definition of the population to whom health benefits decisions apply (ie, defining the “covered population”);
 - 1.1c A statement of the types of rationales and considerations that may be taken into account in making health benefits decisions (see Explanations below).
- 1.2 The organization actively assists in educating enrollees/beneficiaries about covered services and how coverage decisions are made including, at a minimum:
 - 1.2a Providing information on covered and uncovered services using language that is understandable for all relevant populations of enrollees/beneficiaries (see Explanation below);
 - 1.2b Providing an organizational contact person or office to whom enrollees/beneficiaries may turn with questions or concerns about their health benefits;
 - 1.2c Making disclosures available regarding any conflicts of interest among those responsible for designing the health benefits;
 - 1.2d Making information available about financial limitations that affect health benefits design decisions (see Explanations below);
 - 1.2e Disclosing the source of benefits coverage criteria, including the sources of information used to create guidelines.

Expectations of All Organizations Involved in Administering Covered Benefits

- 1.3 The organization assists in educating enrollees/beneficiaries about administrative procedures such as appeals, including at a minimum:
 - 1.3a Providing an organizational contact person or office (eg, an ombudsman’s office) to whom enrollees may turn with questions or concerns about coverage disputes;
 - 1.3b Making available information regarding personal, organizational, financial, or other incentives that affect decisions about coverage;
 - 1.3c Providing to those directly affected by an appeals decision a written description of the decision that includes the rationale(s) used to arrive at the decision.

Table 1 *continued*

Expectations of Some Specific Parties Involved in Administering Covered Benefits

- 1.1s *Practitioners* provide their patients with information about all medically appropriate evaluation and treatment options, whether or not the option is covered.
- 1.2s *Practitioners* inform their patients that a recommended service is unlikely to be covered by insurance, when they are aware of it.
- 1.3s *Practitioners* and *enrollees/beneficiaries* accurately represent symptoms and conditions in seeking coverage for services.
- 1.4s *Practitioners, purchasers, and health plans* engage in clear and consistent communications with each other and with enrollees/beneficiaries, regarding coverage limits.
- 1.5s *Practitioners* and *provider organizations* provide enrollees/beneficiaries information on the benefits, harms, and risks of proposed interventions, including valid information (if available) about local success rates when they differ substantially from literature-derived rates or from regional norms (see Explanations below).

* Note that these expectations are written in the present tense to reflect that they are potentially measurable expectations. Creating measures to determine whether or not an organization is meeting or exceeding each expectation is the goal of the Ethical Force Program™.

** In these tables, except where noted otherwise, “organization” refers to any organization that is formally involved in benefits design and administration decisions, including, for example, practitioner and provider organizations, purchasers, and regulators.

Explanations and Exceptions

- Note that 1.1, 1.2, and 1.3c all call for written documentation to explain the considerations used in designing the health benefits package. The four other content areas in this report are examples of the types of considerations that might be seen on such a list. Openness about the factors considered in making coverage decisions is a core component of accountability for organizations ultimately making these decisions. Through such openness, decisions that may not match stated priorities or that do not meet enrollees/beneficiaries expectations can be explored and, if necessary, improved.
- Using “understandable” language entails presenting information in an understandable format, taking into account health literacy, cultural sensitivity, and what information is likely to be relevant to the population(s) affected by the coverage decisions (ie, the covered population, including vulnerable population groups).
- Proprietary information about financial arrangements may be difficult to release, though general descriptions of payment mechanisms might still be useful and such disclosures are already becoming more common. At the same time, it is not yet clear how best to convey information about potential conflicts of interest. For example, physician disclosure of relatively innocuous financial incentive arrangements, especially in a setting where the patient has no meaningful choice in the matter, may lead to unwarranted patient mistrust and fear, potentially harming patient-doctor relationships and thus preventing high-quality health care.
- Increasingly, studies demonstrate that some procedures, especially new and complex ones, require a good deal of experience to perform safely. If reliable data exist showing relatively poor outcomes at a facility or for a certain practitioner, a remediation plan should be put in place, and relevant patients should be made aware of the situation. Individual health care providers are ethically obliged to inform patients of their training and experience in performing procedures.

Content Area 2.

Participatory

Organizations should purposefully and meaningfully involve all stakeholders in creating and overseeing the processes for designing and administering health benefits.

All stakeholders should have the opportunity to be informed participants in processes that may affect their welfare and the welfare of their families and communities. Incorporating participatory aspects into benefits design and administration is necessary to ensure the legitimacy and quality of coverage decisions.⁵⁰ Participatory processes also foster collaboration and may help address certain prominent patient grievances regarding managed care, which may stem from poor information, unrealistic expectations, and lack of direct input into decisions regarding covered and uncovered services.⁵¹

Legitimacy is enhanced when individuals have a voice in decisions that affect them,^{52, 53} because building patient participation into benefits design and administration processes allows for incorporating political and ethical, as well as market-based, accountability in health care.⁶ Transparency alone is sometimes sufficient for marketplace accountability mechanisms, which rely primarily on the consumer's ability to recognize and leave poor-quality organizations; that is, the power of consumers in the market lies in each individual's ability to "exit" from an organization, taking their business elsewhere. But in health care, choice is often constrained, and leaving may be impossible. Sometimes there are limited providers (such as when employers offer a single health plan). Other times, the nature of an illness itself constrains the individual's ability to switch providers easily. Where exit is not a feasible option, participatory processes can provide patients a voice in improving the product they are receiving.⁵³⁻⁵⁶

Participatory processes also play a role in quality improvement. When all stakeholders are given an opportunity to participate in decision making and expressing their informed views about the value of certain benefits, decision-makers can assess proposed and existing benefits more effectively. In this regard, actively gathering information from stakeholders also serves a dual purpose. It informs plans and purchasers of the needs and priorities of their customers while simultaneously educating enrollees/beneficiaries about coverage dilemmas faced by decision makers.

Finally, promoting participatory processes provides opportunities to discover alliances between beneficiaries, clinicians, health plans, purchasers, and others. In today's health care system, two or more parties may share similar views on an issue without realizing it, or mistrust and

miscommunication may prevent them from working together. Participatory processes can open communication channels between groups who share common goals, leading to more collaboration and cooperative decision-making. For example, clinicians and patients may not recognize when health plan administrators would like to offer a service but purchasers do not wish to pay for it. Similarly, patients may not recognize that they are often (indirect) purchasers themselves and they may not recognize the inconsistency in requesting coverage for services that cannot be provided given the budget that, in a sense, they have allotted. Also of weight in such decisions are the views of benefits consultants and insurance brokers who are charged with helping to allocate resources on behalf of their clients, usually purchasers or insurers.⁵⁷ In short, formal participation of all stakeholders in making coverage decisions allows productive sharing of information and alliance building where mistrust and misunderstanding currently thrive. Long-term relationships will ensue in such a milieu with a shared sense of stewardship for the common good of providing high-quality, efficient, and cost-effective health care for the benefit of all stakeholders.

Limitations

On the other hand, there are important limitations in adopting certain participatory structures—such as direct democratic decision-making (one person = one vote)—in benefits design and administration processes. Daniels and Sabin⁵⁸ suggest that voting among patient and interest groups' representatives would simply aggregate the preferences of those choosing to vote, which might be inferior to basing decisions on "reasons that all free and equal citizens can accept." Participation, even in non-voting forums, is often skewed toward those who are already empowered. For example, the state of Oregon has conducted numerous open public forums to discuss societal health care values since the early 1980s, yet some important constituencies, such as the poor, have not been proportionally represented in these forums.⁵⁹ Moreover, participatory processes must always be attuned to the fact that minorities often have a lesser voice. Even if all parties can participate in deliberations, there might remain concern for the treatment of "medical minorities," such as those with rare or socially stigmatized diseases. Some types of democratic processes can leave minority groups susceptible to the effects of majority rule, resulting in the marginalization of those with significant, but unpopular, health concerns. In light of these concerns, it is important to recognize that participatory processes are not synonymous with direct democratic processes; rather, participatory processes are those that provide meaningful opportunities for education, development of realistic expectations, involvement, and accountability in health care decisions.

Expectations

Measurable expectations in this content area are listed in Table 2. Organizations that are involved in health benefits design and administration can demonstrate the meaningful inclusion of all stakeholders by including relevant individuals in decision-making bodies, actively soliciting input from all stakeholders, and using the information

gathered in decision-making processes. Some participants also have special responsibilities. In particular, practitioners must be responsible for creating a clinical practice environment that fosters trust by encouraging effective communication, enabling shared decision-making, and empowering patients to actively participate in managing their own health circumstances, (Table 2).

Table 2

Expectations of All Organizations Involved In Designing Covered Benefits

- 2.1 Key organizational stakeholders are included as members on decision-making bodies or committees that design health benefits packages and set general coverage rules (see Explanations below). In addition:
 - 2.1a Organizational bodies or committees charged with designing health benefits designate a reasonable number of members who represent the beneficiaries receiving their health care coverage from the organization;
 - 2.1b Meetings of organizational bodies or committees charged with designing benefits hold meetings or other forums to provide all stakeholders an opportunity for input, and record the proceedings;
 - 2.1c Recorded decisions of organizational bodies or committees charged with designing benefits should demonstrate how the views of all stakeholders were considered in benefits design decisions;
 - 2.1d Designated members from each stakeholder group should be selected by fair and unbiased means from each constituency.
- 2.2 The organization engages in outreach activities appropriate to its size to gather information from enrollees/beneficiaries on their needs, values, and priorities, through means that include but need not be limited to:
 - 2.2a Conducting interviews, random sample mail, phone, or e-mail surveys, and/or focus groups of enrollees/beneficiaries that address benefits design issues, such as additional services they would like covered, currently covered services they don't value, copayment and deductible structures, and service delivery mechanisms.
 - 2.2b Providing open forums for enrollees/beneficiaries (eg, open meetings, electronic forums, etc.) to address issues about health benefit packages (note: these are to address large-scale, general issues, not for specific patient cases).
 - 2.2c Encouraging enrollees/beneficiaries to participate in available forums by ensuring that such forums are well publicized and by monitoring the number and proportion of enrollees/beneficiaries attending.
- 2.3 The organization uses its data on enrollee/beneficiary needs, values, and priorities to affect benefits design decisions, through means that include but need not be limited to:
 - 2.3a Providing regular feedback to organizational bodies or committees charged with designing benefits regarding enrollees'/beneficiaries' expressed needs, values, and priorities;
 - 2.3b Providing for revisions of benefits design decisions over time as stakeholders' needs, values, and priorities evolve;
 - 2.3c Providing feedback to enrollees/beneficiaries summarizing their input regarding benefits, access, and development of services.

Table 2 *continued*

Expectations of All Organizations Involved In Administering Covered Benefits

- 2.4 The organization utilizes data on enrollee needs, values, and priorities when considering modifications of appeals and other administrative processes that include but need not be limited to:
- 2.4a Providing regular feedback regarding enrollees'/beneficiaries' expressed needs, values, and priorities to organizational bodies or committees charged with overseeing appeals and other administrative processes;
 - 2.4b Providing regular feedback to practitioners and providers on the expressed needs, values, and priorities of their patients.

Expectations of Some Specific Parties Involved In Administering Covered Benefits

- 2.1s *Practitioners* and *providers* create clinical encounter environments that foster shared decision-making and empower patients to participate in the management of their own health.
- 2.2s *Health insurers* and *health plans* develop and oversee appeals processes that include the input of relevant stakeholders including:
- Patients or their recognized surrogates
 - Licensed practitioners of health care
 - Purchasers securing health care coverage on behalf of beneficiaries, eg, employers

Explanations and Exceptions

- “Meaningful” participation may be in dispute when different parties disagree on priorities or values. In particular, there is a risk that any participant whose views are not controlling may believe that their participation is not “meaningful.” Yet, more often than not, compromises can be reached and rationales articulated for decisions, which can demonstrate that serious consideration has been given to every participant’s point of view. If this occurs, participants are likely to recognize that they have meaningful input. Minutes and other records of meetings and decisions can show that all points of view have been recorded. More importantly, perhaps, performance measures for these expectations are likely to include assessment of participants’ satisfaction with the process and a sense of whether their participation (or the participation of their representatives) is meaningful, which will provide additional impetus to ensure that all voices are heard.
- The number of representatives from each constituency that should sit on any given committee may vary depending on the size of the committee and the issues it is charged to address. There is evidence that having more than one “lay” member of such committees improves the chances that this perspective will be voiced effectively. But in many cases (such as on large committees) it may be appropriate to have more than

two members from the enrollee/beneficiary population. In some cases an argument can be made that the majority of the members of a committee should be beneficiaries/enrollees. Particular attention must also be given to large employers and health plans with divergent employee/enrollee groups, where an assumption that there is a single enrollee/beneficiary perspective is not likely to be correct.

- Enrollee/beneficiary representation on benefits design committees is less problematic than direct “public” or “patient” inclusion in appeals processes, particularly due to confidentiality concerns when reviewing identifiable medical records. The expectations above reflect this fact. Inclusion of enrollees is recommended in the development and general oversight of appeals processes in health plans, but not necessarily in the review of individual cases (except where one’s own care is at issue). (See also Transparent, above.)
- Some useful and highly creative tools are being developed that provide interactive and entertaining methods to assess enrollees needs, values and priorities regarding health benefit options.⁶⁰⁻⁶² Using games and puzzles, these new tools provide opportunities for large groups to become informed participants in the development of health benefit packages.

Equity

Equity is a complex concept with both a folk understanding and several philosophical roots. One way to analyze the concept of "equity" that proved helpful to the Oversight Body in developing this report is the following:

In its dictionary definition, a concern for equity means simply a concern for what is fair, or just. But equity can be thought of as having two distinct dimensions—horizontal equity and vertical equity.

Horizontal (or Positive) Equity: People in similar situations should be treated similarly. For health benefit and coverage adjudication decisions, one's "situation" will be defined by one's ability to afford health care, health status, access to care, medical care needs, and other measures of well being. While one can debate the measure and content of "similar situations," horizontal equity calls for consistent, equal treatment of individuals who are similarly situated. This is important for health benefit and coverage adjudication decisions because it suggests that, within any one organization, enrollees/beneficiaries with similar health needs should be given similar benefit coverage, and that benefit appeals in similar situations should have similar resolutions.

Vertical (or Negative) Equity: People in different situations should be treated differently. Fairness also requires ensuring that people with different health needs have these differences recognized when health benefits are determined and appeals are decided. As with Horizontal equity, one can debate the measure and content of "different situations."

Recognizing these two facets of equity illustrates the importance of integrating concerns about equity (Area 3) with concerns about value (Area 4) and compassion (Area 5). That is, decisions as to how much of a difference between persons merits a different coverage decision may depend, in part, upon the value of the proposed service (eg, the benefit conferred by the proposed service; the cost of the service; the harm in not covering the service; and so on) and compassion (eg, recognizing the values of the enrollees/beneficiaries, which may be expressed through their choices and in other ways; the ability of the individual to obtain the service without coverage or to obtain coverage elsewhere; value judgments of the decision makers; and so on). Though integrally related, these various factors cannot simply be aggregated and addressed using a single abstract principle of equity. Rather, it is important that concerns related to equity, compassion and value each be clearly stated and then assessed in processes which ensure that the full set of appropriate issues implied by these concerns is open for consideration by decision-makers.

Content Area 3.

Equitable and Consistent

Processes for designing and administering health benefits should result in similar decisions under similar circumstances.

Equity calls for systems to provide similar coverage for similarly serious illnesses and conditions. We note also that it is inequitable if meaningful differences in situations are not recognized (see Box). Consistency calls for the uniform application of criteria to all members of a health care system. The ethical significance of equity and consistency in decision making is largely based upon a fundamental argument against inappropriate discrimination. That is to say, it is unfair, discriminatory, and condemnable when similarly situated persons are not treated similarly due to factors irrelevant to the decision at hand. At a minimum, equitable and consistent processes should have a rational connection between the facts and the choice being made, and should not be the result of "arbitrary or capricious"⁶³ decision-making. Equitable and consistent processes seek to achieve logical and reasoned decisions based on appropriate consideration of material and relevant factors.

Consistency and equity are important to the practical acceptability of any resource allocation system. While health organizations build trust when they are consistent and even handed, systems that appear rigged, capricious, arbitrary, or otherwise inappropriately discriminatory will not be broadly acceptable. There are also well-recognized legal reasons to provide consistent and equitable benefits. For example, coverage for one person with a condition generally sets a precedent for future similar decisions that may be legally enforceable.

Limitations

There are risks in focusing too heavily on equity and consistency in the design and administration of health benefits. For instance, too much focus on consistency might hinder progress. Decision-makers might hesitate to cover new technologies or new applications of existing technologies if they must adhere closely to comparable decisions made in the past. Since circumstances in medicine change rapidly, previous decisions often become outdated. In light of advances in medical information and technology, prior decisions can be inapplicable or incorrect and, therefore, unfair to individuals at a later time.

It may also be difficult to record all prior decisions, rationales, and full descriptions of circumstances. There are practical issues in maintaining a "case-law" database of prior coverage decisions, such as space limitations and searching capacity issues, especially when paper records are used. Recognizing that many organizations in the health care system are in the early phases of developing and using such databases, ethical fairness and consistency entails not only a degree of maintaining, referencing, and using prior cases to inform current decisions, but also encouraging continuous quality improvement in this regard.

Expectations

To ensure equity and consistency, coverage criteria should be clear and available in writing. Among other items in this area, we recommend that organizations adopt written criteria for benefits decision-making to facilitate consistency and clarity in determining what is or is not covered and to delineate the criteria used for setting limits on the health benefits provided (Table 3).

In particular, organizations that administer coverage appeals should maintain written records of these decisions, including a delineation of the rationales used in making the decisions and reference to any additional information instrumental in decision-making. Subsequent similar appeals should then refer to prior decisions as appropriate.

The appeals process should also recognize the important, yet sometimes nuanced, distinction between medical necessity/medical appropriateness decisions, which are part of health benefits administration, and appeals decisions that are based on specific prior choices (often made by purchasers) regarding conditions and services that will be covered—that is, benefit design decisions.

Several additional recommendations aim to ensure the independence of appeals processes and to encourage periodic audits of these processes. These recommendations largely reflect evolving legal and regulatory approaches to improving and monitoring the appeals process.

Table 3

Expectations of All Organizations Involved In Designing Covered Benefits

- 3.1 The organization defines in writing (1) the principles and values that guide decisions about health benefits and (2) a general prioritization of different types of medical needs (see Explanations below).
- 3.2 The organization provides at least an adequate basic set of health benefits that is consistent with local community norms (see Explanations below).
- 3.3 Health benefits are provided equitably to all enrollees/beneficiaries with similar conditions, co-morbidities, and abilities to participate in the intervention, regardless of race, gender, socioeconomic status, and other factors lacking clinical relevance.
- 3.4 The organization helps to educate enrollees/beneficiaries in the covered population about the importance of:
 - 3.4a Providing *consistent* health benefits to all members of the covered population with similar diagnoses;
 - 3.4b Providing *equitable* health benefits to the covered population so that similarly serious types of needs, based on impairment of function and risk of mortality, are treated similarly, while important differences are taken into account;
 - 3.4c Recognizing that providing health benefits in certain areas of individual concern may or may not foster an equitable and consistent health benefit across the covered population.

Expectations of All Organizations Involved In Administering Covered Benefits

- 3.5 The organization maintains a retrievable record (electronic or paper) of adjudicated coverage decisions containing enough information to facilitate subsequent equitable and consistent benefits administration.
- 3.6 The organization randomly or regularly audits adjudicated coverage decisions, such as appeals, to verify that no capricious, arbitrary, or discriminatory variations occur.
- 3.7 The organization uses standard and consistent methodologies to collect, analyze, and evaluate clinical evidence of efficacy and other relevant information used in benefits administration.
- 3.8 The organization uses objective (ie, not personally or financially involved) clinical experts in appeals and other adjudication processes.
- 3.9 The organization helps to educate beneficiaries/enrollees in the covered population about:
 - 3.9a Processes available to enrollees to appeal coverage decisions
 - 3.9b Options available when useful services are not covered
 - 3.9c An organizational contact person or office (eg, an ombudsman's office) to whom enrollees may turn with questions or concerns regarding appeals or other adjudication decisions (see also Transparent, Table 1).

Table 3 *continued*

Expectations of Some Specific Parties Involved In Administering Covered Benefits

- 3.1s *Practitioners* recognize that their patients' involvement in an insurance pool entails membership in a group for which the practitioner shares some responsibility and accountability for the equitable utilization of limited resources.
- 3.2s *Patients* and *purchasers* understand that their involvement in an insurance pool entails membership in a group that shares stewardship for the equitable distribution of limited resources.

Explanations and Exceptions

- Statements of principles and values should provide general guidance about what the health benefits package is intended to achieve. A written prioritization of medical needs that will be covered for the population is also desirable. It should address more specific factors, such as likely benefits and risks of proposed services and the role that the severity of illness (degree of disability, risk of death, etc.) and individual and community values play in making coverage decisions. Such a prioritization list might specify, for example, that treatments offering meaningful opportunities to cure life-threatening illnesses would be given high priority for coverage. Such guidance should be recognized as necessarily somewhat vague, to allow for appropriate flexibility in interpreting cases under varying circumstances (see also Content Area 5: Compassion, below).
- An “adequate basic set” of benefits may vary from place to place and time to time, since it should be consistent with the expressed values and priorities of beneficiaries/enrollees (determined through mechanisms such as those described in Content Area 2: Participatory). Benefits should also change with the evolution of sound medical practice and resource constraints (for example, with regard to cost-effectiveness, as described in Content Area 4: Sensitive to Value). Therefore, performance measures for this expectation are likely to include surveying practitioners and patients to determine whether offered benefits are meeting the basic needs of the population.
- Absolute resource constraints in some instances, such as for very small groups, may preclude coverage for high-priority, even lifesaving, services. When this occurs, it often reflects a moral failure of the health care system as a whole, rather than a moral failure of the individual or organization purchasing or offering coverage. However, particularly in such instances, living up to the remainder of the expectations set forth in this report becomes most important. When the most difficult resource allocation decisions must be made, pressure should increase to ensure (1) the participation of all stakeholders, (2) clarity in what considerations will come into play in making the decision, (3) clarity in setting priorities, and (4) transparency of the entire process.

Content Area 4.

Sensitive to Value

Processes for designing and administering health benefits should take into account the net health outcomes of services or technologies under consideration and the resources required to achieve these outcomes.

In general, health benefits packages should be designed and administered to provide the greatest benefit to the most patients at the lowest cost, or, in other words, to provide the greatest value. In this context “value,” by definition, includes consideration of both benefit and cost. This is often signified by using the formula $\text{Value} = \text{Benefit}/\text{Cost}$. For example, one treatment has greater value than another if it provides greater benefit to patients and costs the same, or if it has a lower cost but provides the same level of benefit. The moral philosophical framework underlying this drive to maximize value is a type of consequentialism, which calls for seeking the greatest good, in terms of health, for the greatest number of people given available resources.⁶⁴

The value provided by potential health services should be considered in both the design and administration of health benefits packages, though often in different ways. Ideally, designing a benefits package should entail an analysis of the population-based value of each candidate service. In the absence of other considerations, services with little or no health value—those that are not known to be effective and do not improve health outcomes, such as purely cosmetic services—should be the first items excluded from coverage. The Ethical Force Program™ realizes that some very costly services are clinically effective and improve net health outcomes (such as organ transplantation), yet sometimes are excluded from coverage solely because purchasers are unable to afford the premium cost necessary to include these services in the benefits package (see the Explanations and Exceptions notes under Content Area 3, above).

In the realm of administration, including the adjudication of coverage disputes for individuals, some services may fall under covered categories yet have no known efficacy. They should not be covered, regardless of cost, because they do not provide value (value = benefit/cost). For example, “physician services” may be a covered category of service, but administration of a coffee enema by a physician would not be covered because it is not known to be effective.

Under such value-based analyses, when alternative services have comparable efficacy the lower cost service would preferentially be covered *unless* an individual patient has concurrent disease, allergies, or other factors that make the lower cost treatment less effective for that patient. Another way that consideration of value might affect both design and administration of a benefits package is when considering the relation between the quality of the service performed and its efficacy; that is, treatments that are not performed proficiently and appropriately will be less effective and have less value. Thus, it is appropriate to recognize higher quality settings or providers in both the design and administration of health benefits, such as covering certain complex procedures only in centers of excellence.

Value analysis in health care should be a two-step process. The first step involves estimating the clinical outcomes associated with the service or technology in question; that is, assessing the potential benefits, harms, and risks that result from use of the proposed service. At this stage, “outcomes” means evidence-based outcomes measured in clinical practice or through research. Assessment of clinical outcomes is not affected by individual or group opinions or preferences, nor is it affected by consideration of costs. The second step involves incorporating information about costs and comparing potential outcomes for alternative services to determine whether benefits outweigh harms and justify costs for a specific population or patient. This latter analysis should incorporate and welcome the role of group and individual preferences and values (some of which can be derived through participatory processes, as noted in Content Area 2: Participatory, above).

A common mechanism for comparing the overall “value” offered by alternative services in policy making is to use cost-effectiveness analyses (CEA). CEA are generally used to compare different approaches to the same problem (for example, comparing yearly to every-other-year mammography for the detection of breast cancer). In health care, it has been recommended that CEA results generally be presented as the cost of preserving a “quality-adjusted” year of life (or QALY) for each option examined.⁶⁵ Using CEA to inform the design and administration of health benefits packages has been promoted for several reasons. First, in

some cases, CEA can give a clear and direct answer as to which of two proposed therapies is “better.”⁶⁶ Second, declining to cover services that are not relatively cost-effective may prevent harms, both because ineffective therapies can be dangerous and because paying for such services reduces the pool of available resources to pay for other, more effective treatments. Third, it can be argued that using cost-effectiveness as a criterion in resource allocation may improve distributive justice (each individual receiving his or her due share of resources). If only cost-effective services are covered, then resources go only to patients who will obtain at least as much benefit as those who might otherwise have a claim on the resources. Assuming that an individual’s claim to health care resources rests on the degree to which the resources will provide a benefit (an assumption, it should be noted, that would not be universally accepted), then making coverage decisions based on cost-effectiveness would improve the just distribution of resources.

Limitations to the Use of Cost-Effectiveness Analyses

The value of a service, broadly construed, should always be taken into account in making coverage decisions, but there are important practical limitations in the appropriate use of CEA to make these decisions, especially at the individual level. First, while considering information about cost-effectiveness can potentially contribute to making decisions that will improve the efficiency of the health care system in attaining its goals, it is important to specify what these goals are. Whether a treatment is “effective” or not may depend on what the intended effect of the treatment is. For instance, a CEA based on years of life saved is probably an inappropriate way to assess different modalities of palliative end-of-life care. The intended effect, or outcome of interest, for palliative care is not life extension but improvement in quality of life.

Second, good CEA are difficult to perform. Necessary patient data are often unavailable. Many factors can affect the degree to which a treatment looks “effective,” such as the population studied and the other treatment(s) it is compared with, making the techniques of CEA complex and susceptible to tampering.⁶⁷ Performing scientifically-sound CEA is also expensive, and even high quality CEA become outdated. An enterprise to perform and maintain independent, updated CEA for a comprehensive set of medical services would be very useful, but it would probably require substantial and ongoing public and private investment. In the meantime, many organizations that design and administer health benefits are not equipped to perform high quality CEA.

In addition to these practical concerns, CEA pose ethical concerns. Most CEA do not incorporate values such as mercy, compassion, and equality of opportunity, which may be as or more important to society than cost-effectiveness.⁶⁸ While CEA can be weighted to emphasize these virtues, such CEA might then be criticized for having been crafted to obtain desired answers.⁶⁹ Strategies to better address these concerns are being developed, but each strategy faces technical, organizational, and psychological hurdles to its implementation.⁶⁹ In part these hurdles reflect the fact, as noted above, that CEA are essentially tools for pursuing a consequentialist moral philosophy. Hence—like utilitarianism, which is the best-known consequentialist moral philosophy—using CEA to make coverage decisions can be criticized for not respecting individual integrity and autonomy.⁷⁰ For instance, the parties most directly involved in health care delivery—patients and practitioners—may feel violated if they are denied the ability to make treatment decisions based on their own values and unique circumstances. At the same time, it should be noted that personal preferences individual clinicians or patients might have for services that are contractually excluded from coverage or have no proven clinical benefit cannot be recognized by a purchaser or provider with ethical and legal obligations to allocate limited resources rationally and equitably.

A related concern is that any population-based assessment of value, including the use of CEA, risks the perception that legitimate professional judgment or patient preferences are being ignored. To address this, while the most cost-effective treatment should generally be the preferred treatment, coverage decisions for individuals should ultimately take their unique clinical and functional needs into account. Where two services (or sites of care, or modes of delivery) are comparably effective for a given patient, the coverage decision could be made on the basis of cost-effectiveness. But for a patient with comorbidities or other factors that reduce the clinical benefit of one treatment option, an alternative treatment with higher initial costs might, in fact, provide greater value and even be more cost-effective.

Finally, some outcomes of cost-effectiveness analyses may be intuitively unacceptable. For example, the original use of CEA to develop the Oregon Health Plan's list of covered services suggested that capping teeth was a more effective use of resources than providing coverage for appendectomies. Such outcomes are partly the result of flawed methodologies, but they also suggest that values other than simple aggregate costs and benefits must be included in making coverage decisions.⁷¹

Expectations

The best available information should be used to assess the value provided by each health service under consideration. The ability of CEA to quantify the trade-offs involved in choosing alternatives to reach a desired health outcome makes them a valuable source of information when deciding which services to cover. But, in light of the strengths and limitations of CEA identified above, CEA should play a constrained role in designing covered benefits and a very limited role in administration processes (Table 4). Recently, standardized methods have been developed for performing CEA.⁶⁵ It is particularly important to use these standard methods—such as the development of a “reference case” using the societal perspective—when performing CEA to assist in resource allocation decisions.⁷² It is also important to recognize that CEA will be of most value when comparing two treatments or tests that are expected to have similar efficacy but substantially different costs. When one treatment is clearly much more effective than the alternatives, especially for a serious condition, a CEA is unlikely to yield information that will alter decision-making, and thus is not warranted.

Ultimately, administering a health benefits package for individual patients should entail incorporating evidence-based knowledge into clinical practice. If alternative services under consideration are covered benefits, then providing the service that produces the greatest net health outcome, or greatest value (when health outcomes are similar), will be in the best interests of the patient, the covered population, and society.

Table 4

Expectations of All Organizations Involved In Designing Covered Benefits

- 4.1 In determining whether to include proposed new services, technologies, or modalities in a health benefit package, the organization considers their value for the covered population by assessing:
 - 4.1a Their benefits, harms, and risks using the best available clinical and scientific data;
 - 4.1b Their net health benefits compared to those of the best existing alternatives.
- 4.2 When the net health benefit of a proposed new service, technology, or modality significantly exceeds that of the best existing covered alternative, the new service is covered (see Explanations below).
- 4.3 When the net health benefit of a proposed new service, technology, or modality is comparable to that of the best existing alternative, the organization reviews (or performs, if necessary) cost-effectiveness analyses to compare the new technology to the best existing covered alternative(s). Services that are more cost-effective are covered preferentially as first-line services for the population, but exceptions may be made in individual circumstances. (see also Content Area 5 below).
- 4.4 Cost-effectiveness analyses, when performed, are performed using standard and consistent methodologies.⁶⁵
- 4.5 When previously performed cost-effectiveness analyses are reviewed, they are assessed for whether they were performed using standard and consistent methodologies.⁶⁵
- 4.6 In assessing the overall cost-effectiveness of proposed interventions, the organization considers the health of all relevant communities, including communities outside the covered population (see Explanations below).
- 4.7 The organization periodically reviews cost-effectiveness assessments when:
 - 4.7a Relevant new information arises that might significantly impact previous analyses;
 - 4.7b More than 5 years pass.

Expectations of All Organizations Involved In Administering Covered Benefits

- 4.8 Financial and other costs and benefits that may lie outside the immediate organization (including costs and benefits to the patient, his or her caregivers, employer, family members, and so on) are considered in assessing whether to cover proposed interventions for individuals (see Explanations below).
- 4.9 For conditions and categories of service that are included in the covered benefits, a specific technology or modality is covered when its net benefit significantly exceeds that of the best-existing alternative for the given individual, taking the unique clinical and functional needs of the individual into account.

Expectations of Some Specific Parties Involved In Administering Covered Benefits

- 4.1s *Practitioners* and *provider organizations* give the most accurate information available on benefits and costs to organizations performing CEAs.

Explanations and Exceptions

- Organizations often choose not to cover specific conditions or types of services even though they clearly provide benefits, such as dental care, assisted reproduction, eyeglasses, certain cosmetic surgeries, and so on. For such uncovered conditions and types of services, new options might arise that are more effective than existing (uncovered) alternatives, but these new options need not generally be covered. Occasionally, the advent of a new and effective treatment option will justify a fundamental modification to the benefits package to cover a previously excluded condition or type of service, but such breakthrough treatments are uncommon. However, for a covered condition or type of service, new services that are shown to be significantly more effective than covered alternatives should preferentially be covered. CEA should play a role in these coverage decisions when the relative efficacy of two or more options might be similar but cost differences are expected to be large.
- Performing cost-effectiveness analyses using a “reference case” from the “societal perspective” is crucial for making different cost-effectiveness studies comparable.⁶⁵ It may also yield important information for stakeholders involved in making coverage decisions. For example, if a decision not to cover a service in the hospital will result in increased home care costs for families, decision-makers should recognize this fact. On the other hand, Ethical Force recognizes that a fundamental issue in resource allocation in health care today is that savings accrued in one sector may mean additional costs in another.⁷² This “externalizing” or “shifting” of costs within the health care system leads to overall inefficiencies. Though it is beyond the scope of this report to address this issue fully, this sort of cost-shifting is important, and recognizing it when it occurs may be a step towards addressing it.⁷³
- In general, it is preferable that CEA be performed by those without a direct financial or personal interest in coverage decisions, to ensure their objectivity.⁶⁷ For this reason, proposals to create independent national or regional boards to perform these analyses are attractive.⁷⁴ The very high cost of performing scientifically rigorous CEA and keeping them up to date also argues for a public-private partnership organization that could be charged with this large task.

Content Area 5.

Compassionate

The design and administration of health benefits should be flexible, responsive to individual values and priorities, and attentive to the most vulnerable individuals and those with critical needs.

Compassion is a critically important human value in health care, and it should be a primary consideration when designing and administering health benefits packages. Certain groups are especially vulnerable (see the Glossary for a definition of “vulnerable populations”), but illness and financial stress can combine to reduce virtually anyone’s capacity for self-help. Very often, it is when we are at our most vulnerable that we are also most reliant on our health insurance benefits. The intent of this final content area is therefore to reflect upon, and in a sense summarize, the four prior content areas. Our hope is that organizations following the recommendations already listed will demonstrate compassion and attention to vulnerable populations by clarifying how and why exclusions are chosen, involving all relevant parties in making these decisions, and providing benefits equitably, consistently, and with a view towards maximizing the health benefits obtained from covered services given limited resources. This final content area makes an additional case for specific consideration of individual needs, values, and priorities and especially for ensuring the provision of appropriate care to the most vulnerable individuals.

Modern health care requires a vast range of services, some of which generally receive higher priority for coverage. For example, as noted in Content Area 3: Equitable and Consistent, the severity of illness (degree of disability, risk of death, and so on), the likely benefits and risks of a proposed therapy, and the effects of treating or not treating a condition on the use of health resources or even on productivity all may be appropriate factors to consider when prioritizing the kinds of services that should be covered or excluded. But while each community may prioritize these factors differently, compassion dictates that health care distribution not be solely formulaic and population-based—that is, uninformed by individual variations in priorities, values, and medical needs. Administration of covered benefits should thus remain flexible and responsive to extraordinary individual circumstances. Seeking health care can be an intensely personal experience, undertaken at a time of extreme vulnerability and need. Individuals seeking health care appreciate and expect a certain level of respect for their personal beliefs and values. They expect practitioners, providers, employers, and insurers to help

them share in the decision-making processes of health care by providing adequate information and offering appropriate choices. When respect is not forthcoming and choices are not offered or honored, patients may feel abused or violated by what they view as an uncaring system or uncaring practitioners. This can result in feelings of fear and mistrust, which can have adverse effects on health outcomes.³⁷⁻⁴¹

Although the goals of organizational efficiency and social utility may sometimes compete with the goal of responding to individual needs and values, the moral sensitivity of individuals within health care organizations should foster a corporate sense of obligation to be responsive. Compassion is an innate human emotion, which creates an undeniable “rule of rescue” among us. This term, coined by bioethicist Al Jonsen, describes one’s sense of duty to immediately rescue endangered life—an imperative that cannot be “expunged from one’s collective moral conscience” even by the “most evangelical utilitarian.”⁷⁵ As a result of this imperative, extraordinary expenses are borne by society to rescue trapped climbers, children who have fallen into wells, and seafarers caught in storms. Another writer, David Hadorn, notes that the “societal discomfort and shame” that would result from failing to attempt to save endangered individuals suggests that rescues create in society “a sense of fairness” and comfort in the shared recognition that each individual is valued.⁷¹ Thus, paying special attention to those with critical needs builds a safety net and promotes social cohesion and a sense of community reliability. A compassionate health care system can create a sense of security for members of society, who are reassured that special efforts will be made to help any member who falls victim to the extremes of illness.

It must also be recognized that there is great variability in individual responses to illness and treatment. Decision-making processes that incorporate compassion will be flexible enough to adapt to this variability, and, in so doing, may be more efficient and effective as well as more humane. Health care professionals have the opportunity to observe the human variability of illness and response to therapy and can learn to recognize subtle or indirect clues. Fostering the special role of professionals as patient advocates can capitalize on their accumulated knowledge and clinical insight during the process of designing and administering a health benefits package.

Finally, compassion in coverage decisions is consistent with the purposes of health insurance. Insurance is expected to provide help in times of crisis, when there is great individual need and vulnerability. The public is not likely to perceive as adequate, or fair, insurance programs that do not respond well to the concerns of people with special needs and catastrophic illness.

A Note on Protecting Vulnerable Populations

Some patient groups—such as the physically or mentally disabled, limited or non-English speaking, geographically or culturally isolated, chemically-addicted or dependent, seriously or chronically ill, homeless, frail or elderly, and children—confront substantial barriers to the safe and appropriate use of health care services. These groups are generally considered to be *vulnerable populations* (see Glossary) because it is difficult and sometimes impossible for them to act to protect their own health care interests. They are less likely to participate meaningfully in benefit design, pursue appeals, be aware of coverage limits, select thoughtfully from among benefit options, and perform other self-protective actions, compared to those with greater social, physical, mental, and financial resources.

Recommendations throughout this report reflect concern for vulnerable populations. For example, recommendations under Transparency provide advocates for vulnerable populations with the information necessary to make an effective case on their behalf. In addition, the Transparency section notes that while every health benefits package has exclusions and limitations, it would be unethical to intentionally design an exclusion so that it is unclear to the vulnerable population(s) to which it would most likely apply (see, for example, recommendation 1.2a). The recommendations under Participatory make the routine and proactive collection of feedback from members of vulnerable populations more likely. However, this section on Compassion is especially pertinent because it calls on organizations to focus attention specifically on the needs of vulnerable populations and the ethical obligations that every participant in health care holds towards ensuring their fair treatment (see especially 5.1, 5.6b, 5.7, 5.2s, 5.3s and 5.6s).

The Oversight Body is aware that caring for vulnerable populations can be expensive and is sometimes poorly reimbursed, since these populations generally have few financial resources. Yet for the health care system to have ethical integrity, protection of vulnerable populations must receive specific attention as an issue of highest priority. A health care system that does not protect its most vulnerable patients is failing medically, ethically, and socially at the most fundamental levels.⁴⁷

Limitations

Measuring personal characteristics of compassion is very difficult, and measuring organizational compassion is even more difficult. For the most part, however, a sense of compassion is experienced by the giver and receiver of compassionate acts. Patients' subjective assessments of satisfaction and trust in organizations may provide a qualitative measure of whether these entities respond compassionately to patients in times of greatest need. Likewise, surveys of practitioners and providers can determine their views about the level of compassion and flexibility shown by various organizations that may offer services or benefits to patients.

More important than measurement challenges are issues related to resource limits and equity. Responding to every individual need every time would be economically prohibitive in a health care system that sometimes has the technological capability to sustain failed organ systems indefinitely. Rescue therapies, such as aggressive treatment in extreme medical circumstances, often have a low probability of success and typically are very expensive. Some treatments and services requested by individuals are not consistent with evidence-based standards of care; such requests need to be considered compassionately but realistically in light of medical evidence, the patient's clinical situation, and the expected outcome. Making case-specific judgments based on individuals' unique values or priorities also will not yield consistent decisions about the use of resources, and is thus potentially unjust to others in similar circumstances. Compassion can even backfire: providing unique and expensive services to those with special needs might create a sense of inequity and mistrust if it appears that others will not receive attention to their basic health care needs as a result.

Expectations

A compassionate system should take special care to protect its most vulnerable patients and recognize an ethical obligation to secure health care for those individuals who require immediate treatment, and at the same time recognize the importance of fair distribution, quality, and cost effectiveness. To minimize inequities, an ethical system will ensure that benefits administration takes into account individual circumstances informed by the best available scientific evidence, professional judgment, and using consistent criteria and a uniform process (See Content Area 3: Equitable and Consistent).

One important way in which benefits packages can respond to individual needs and preferences is including options for supplemental coverage (Table 5). Compassion for special needs can also be expressed through fair and efficient appeals processes, which include fostering patient advocacy by professionals. As noted above (Content Area 1), open and honest communication is critical throughout health care, including in the design and administration of covered benefits. Patients, practitioners, purchasers, and plan administrators should communicate openly and honestly among themselves, recognizing a role for advocacy and awareness of the legitimate needs of all stakeholders. All parties should participate in this interactive process with an understanding that compromise may be both necessary and ethically appropriate.

Table 5

Expectations of All Organizations Involved In Designing Covered Benefits

- 5.1 The organization measures the health effects of benefits design decisions (including the use of exclusions, waiting periods, service caps, and copayments) on *vulnerable populations* (see Glossary).
- 5.2 The organization specifically addresses the priority given to services for the small percentage of cases that have catastrophic medical needs.
- 5.3 The organization monitors the level of satisfaction that practitioners and beneficiaries have with the availability of services and the interaction necessary for successful access.
- 5.4 The organization provides a choice of supplemental benefits options that are appropriate for individuals and groups within the covered population.
- 5.5 The organization provides information to enrollees/beneficiaries so that they can make informed decisions about supplemental benefits options.
- 5.6 The organization tracks the uptake and utilization of supplemental benefits options to inform revisions to the basic benefits package.

Table 5 *continued*

Expectations of All Organizations Involved In Administering Covered Benefits

- 5.6 The organization provides a process for the resolution of coverage disputes that is efficient and fair, with features that include but need not be limited to:
 - 5.6a Processes for adjudicating disputed benefits that are rapid and commensurate with the exigency of the case in question, according to the available information;
 - 5.6b Professional practitioners who are encouraged to participate in the adjudication process with or on behalf of patients under their care;
 - 5.6c Final adjudications of disputed coverage decisions involving determinations of medical appropriateness, effectiveness, or need, (eg, medical necessity or investigational treatment decisions) that are decided by individuals and/or groups with appropriate clinical expertise;
 - 5.6d Final adjudication of disputed coverage decisions involving determinations of medical appropriateness, effectiveness, or need, (eg, medical necessity or investigational treatment decisions) that are decided by individuals and/or groups with no direct personal or financial stake in the outcome of the dispute.
- 5.7 Following adjudication of coverage disputes, regardless of the outcome, the organization provides a mechanism for all stakeholders to express their degree of satisfaction with the fairness of the process for handling the dispute (see Explanations and Exceptions below).

Expectations of Some Specific Parties Involved In Designing Covered Benefits

- 5.1s *Purchasers* and *health plans* monitor provider organizations for their responsiveness to enrollee needs and values.
- 5.2s *Provider organizations* develop and monitor programs to address the needs and preferences of vulnerable populations (see Glossary).
- 5.3s *Provider organization* marketing efforts are nondiscriminatory and promote the organization to all eligible populations, including vulnerable populations and those with complex needs.
- 5.4s *Practitioners* inform provider organizations and purchasers if benefits packages are failing to meet their patients' needs.

Expectations of Some Specific Parties Involved In Administering Covered Benefits

- 5.5s *Provider organizations* and *practitioners* respond promptly to patient and family concerns about coverage decisions.
- 5.6s *Practitioners* advocate on behalf of patients who need services that may not be covered, either to obtain coverage, alternative services, or other methods of coverage.

Explanations and Exceptions

Organizations should collect information from stakeholders who have been involved in adjudication of a coverage dispute and use this information to improve the process. Some of the ways in which feedback from stakeholders can be meaningfully incorporated to improve the decision-making process are outlined in Content Area 2: Participatory.

Conclusion and Invitation

Health care delivery is a moral enterprise, grounded in a covenant of trust.⁷⁶ To retain this trust and protect potentially vulnerable patients, health care requires a *shared* set of expectations for ethical behavior, applicable across the full range of health care participants. Health care delivery organizations, purchasers, patients, and clinicians must be accountable to each other for identifying and then implementing these shared expectations. This report represents the unique approach of Ethical Force in bringing together representatives from a broad spectrum of participants in health care to form a framework for evaluating and improving the fairness of health care coverage decisions, including a set of specific, measurable expectations for performance.

Ethical Force has developed this consensus report to serve as the precursor to developing useful tools for measuring the fairness of health care coverage decisions within organizations. The recommendations are that health benefit packages should be designed and administered using processes that are (1) transparent, (2) participatory, (3) equitable and consistent, (4) sensitive to value, and (5) compassionate. While many organizations are working along these lines, there are significant current needs in each area. Coverage decisions should be explained in writing and denials of coverage should always be accompanied by an understandable statement as to the rationales used in the decision. There is a need for improved beneficiary/enrollee participation in the design of health benefits packages. Organizations should ensure demonstrable consistency in how benefits packages are administered, while allowing for a fair measure of flexibility for individual circumstances and special protections for, and monitoring of, the most vulnerable individuals and groups. Within this framework, Ethical Force recognizes that costs, though important, will not be an overriding factor in most decisions.

Affecting the health care system with these recommendations is an ambitious goal, and Ethical Force recognizes the practical barriers to achieving this goal given the realities of our current, dynamic health care system. Limited resources in health care must be used to address many important concerns. Developing and using performance measures based on this report will require resources, and any new expenditures, even those demonstrating a strong commitment to ethics in health care, must be well researched and justified.

The next steps planned for this report will involve conducting careful research to create and evaluate performance measures derived from the expectations listed here. Ethical Force will use rigorous evaluation research tools and field testing to ensure that its performance measures are valid, reliable, meaningful, and feasible to implement at a reasonable cost. Rigorous evaluation of the performance measures can ensure that the effort and resources expended in using them will provide value commensurate with the costs incurred.

Ethical Force also recognizes that even ideal performance measures cannot provide a guarantee of uniformly fair decisions or ethical organizations. However, it is reasonable to believe that organizations adopting this framework and monitoring the listed expectations might be viewed more positively than those that do not. At the very least, we hope this consensus report will prompt a wider array of participants in the health care system to consider the ethical norms and ideals that Ethical Force has suggested are important in the design and administration of health benefits packages.

Finally, Ethical Force aims to improve health care by fostering the ethical behavior of all participants. As the program continues to develop, the support it has received from a wide variety of organizations and individuals affirms the view that ethics is at the core of quality health care. The strength of Ethical Force will always stem from the broad and diverse support of experienced individuals coming together to build consensus and accountability through shared expectations. Organizations interested in the goals of Ethical Force can take several specific steps that will help further this work. Organizations are now invited to participate in the efforts of the program through (1) collaborating in field testing and (2) providing funding to support field testing and the dissemination efforts of this not-for-profit program. We invite all participants in the health care system to carefully examine the framework and recommendations in this report and to contact the Ethical Force Program™ with comments, criticisms, and proposals for evaluation and implementation. Every reader is invited to participate in this unique process as the recommendations in this report are transformed into practical tools for better health.

Glossary

Accountability: The procedures through which one party provides the justification for its action and is held responsible for this action by another party with an interest in it.

Adjudication: The process by which appeals for coverage are made and decided.

Administration: The various processes by which decisions are made concerning covered benefits for specific individuals, including adjudication of appeals. Benefit administration is undertaken by individuals and groups, including benefits consultants, benefit management groups, benefit administration groups, self-insured purchasers, health plans, provider groups, and so on.

Beneficiary: A member of the population covered by a health insurer. In employment settings, the term applies to all employees and their family members enrolled in employer-sponsored health plans. When an employer is self-insured, beneficiaries and enrollees may be the same.

Beneficiary Representative: A beneficiary who participates as a formal representative of the covered population on committees, task forces, etc. charged with providing input into health benefits design decisions.

Benefits Adjudication: See Adjudication.

Benefits Administration: See Administration.

Benefits Design: The process of selecting health benefits coverage under an insurance plan, including under managed care health plans; benefits design decisions include such issues as what types of services will be covered in what settings, as well as copayment amounts, coverage caps, and so on.

Content Area: In performance measurement, an aspect of a domain of measurement that must be considered for a full assessment of quality in the domain.

Covered Benefits: The selected benefit coverage areas for enrollee/member/patient, as determined by the contractual relationship between the purchaser and the health plan/insurer.

Domain of Ethics: An area of ethical concern that is potentially amenable to the development of shared norms and subsequent performance measurement.

Enrollee: An individual who is eligible to receive coverage from a health plan, including managed health care plans; may be either a patient or a potential patient.

Enrollee Representative: An enrollee who participates as the formal representative of a group of enrollees on a health plan committee, task force, etc.

Health Care Organization: Any organization that directly facilitates or provides health care to individuals. Examples include health plans, physician groups, and hospitals, but do not include purchasers or regulators.

Health Plan: An organization involved in both the financing and delivery of medical care.

Measurable Expectations: A defined and measurable standard for performance.

Performance Measures: A mechanism to assess whether or not, or to what extent, an organization or individual is living up to defined standards of performance.

Practitioners: Physicians, nurses, and other individuals who provide direct health care services.

Providers: Organizational entities that directly provide health care services to patients, such as hospitals, clinical groups, nursing facilities, and so on. Some, but not all, health plans are providers.

Purchasers: Organizational entities that are responsible for contracting with health insurers to provide defined packages of health care services for defined populations of beneficiaries.

Self-Insured Employer: An employer/purchaser of health coverage that also bears the financial risk for the insurance product.

Vulnerable populations: Groups at increased risk for adverse health outcomes due to a relative inability to safeguard their own health care needs and interests and to safely and effectively access the health care system. Vulnerability can be due to social factors (such as financial, cultural, or language barriers, or discrimination within the health care system), health status (such as physical or mental disability), environmental factors (such as geographic barriers), or combinations of all three. Vulnerable populations may include, but are not limited to, those who are physically or mentally disabled, limited or non-English speaking, geographically or culturally isolated, chemically-addicted or dependent, seriously or chronically ill, homeless, frail or elderly, children, and the un- or under-insured.

Appendix A:

The Expert Advisory Panel on Benefits Determination

(Affiliations listed for identification only)

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United Auto Workers

Mary Jane England

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The Hastings Center

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Appendix B:

Ethical Force Program™ Mission and Goals

Ethical Force Program™ Mission

The mission of the Ethical Force Program™ is to improve health care by fostering the ethical behavior of all participants. The Program identifies and promotes ethical expectations and performs research to develop valid and reliable measures of their achievement.

Ethical Force Program™ Goals

Through the collaborative involvement of all major participants in health care, the Program aims to achieve three goals:

- To identify and promote ethical expectations for all participants in health care;
- To develop valid and reliable measures of achievement of ethical expectations;
- To encourage the widespread adoption and use of these expectations and measures.

Appendix C:

Refining the Scope of the Consensus Report

1. Ethics and Access to Health Care

Health care coverage decisions occur at several levels: the *aggregate level* (addressing questions of access to health insurance, resources allocated to health care in comparison to other social priorities, and so on); the *intermediate level* (addressing questions of benefits package design for defined populations); and the *individual level* (addressing coverage decisions made “within health care institutions, including those at the bedside, about whether or not a treatment should be started or discontinued”).⁷⁷ This report focuses almost solely on the latter two types of coverage decisions. Yet the decision to set aside first level issues—that is, broad issues of health care access—proved very contentious with the Ethical Force Program™ Oversight Body. The first part of this appendix briefly outlines the arguments surrounding this decision.

Access to health care is extremely important on both a practical and a moral level. It also poses compelling challenges, because addressing issues of access requires consideration of large-scale social issues from many different perspectives. For example, why do a growing number of Americans lack insurance coverage? Why don't some patients access care that would be covered? Why do some parts of the country remain under-served? And why did many problems of health care access continue to worsen during a prolonged period of extraordinary economic expansion in America?^{78, 79} These issues frame a debate that poses profound challenges to the moral fabric of our society.^{27, 78}

Within the broad topic of access, perhaps the most controversial issues comprise access to health insurance coverage. To some experts, including several involved with this project, the very existence of voluntary, commercial, employer-sponsored, and risk-rated insurance poses insurmountable obstacles to ethical health system resource allocation. It is posited that such a system will not provide access for, and may instead victimize, highly vulnerable individuals and groups.⁸⁰⁻⁸² These experts believe that only a mandatory enrollment system, without risk-rating, can achieve universal access to insurance coverage, which they consider to be a precondition for any fair and ethical system for resource allocation in health care.

Conversely, other experts argue that any solution that is involuntary, noncommercial, and requires community rating is politically unrealistic, practically undesirable, and perhaps unethical. For example, some are convinced that

the end-result of government financing would be an unacceptable rationing of health care services and loss of autonomy for patients and practitioners. Of course, the first group disagrees with this prediction, pointing to the health care systems of affluent countries like the Netherlands, Switzerland, and Germany, which offer universal health coverage to their citizens while maintaining considerable autonomy for physicians and patients. The second group responds by noting differences in culture, geography, and population dynamics between the United States and other nations. And so the arguments over access to health insurance continue. Clearly, these competing visions for addressing access to insurance coverage are strongly held, and no ready resolution for American health care is at hand.

Despite these compelling large-scale issues—and the undeniable allure of attempting to reach consensus by using the Ethical Force framework—the Program's decision to focus only on benefits design and coverage administration has distinct advantages. Perhaps most important, focusing on benefits design and administration issues allows consideration of these issues within *defined* systems; that is, it permits the allocation of resources for particular “covered populations,” such as enrollees in a single health plan, employees of a single company, or members of a certain purchasing pool to be addressed. Crafting measurable expectations for ethical action within such defined systems seems significantly more manageable than developing a workable plan for universal insurance access across the United States. Indeed, some barriers to access might be more meaningfully addressed within such defined systems. For instance, transportation or language problems in a local population might be specific to that community and thus more easily identified and resolved at the local level.

Two important concerns were raised regarding the report's focus on coverage decisions within defined covered populations. First, improving the “ethical legitimacy” of coverage decisions made within small, isolated pieces of a structurally unfair system could lead to complacency about the system as a whole, especially if it failed to challenge, or worse, masked, the inequities of the underlying system. For example, an organization might do a very good job of allocating resources for health care within its covered population, but intentionally exclude from this population the ill, infirm, or those at higher risk of illness. Clearly, a set of ethical expectations that facilitated or rewarded this behavior would have failed in an important way. Second, it is frequently unclear how to define “covered populations,” given the transience of individuals and groups in insurance programs in the United States. At least partly for this reason, finding a sense of community in even relatively discrete parts of the American health care system has been a major challenge.^{83, 84} This has had important negative effects; one suggestion is that the absence of stable health

plan communities has hindered the development of effective managed care.⁸⁵

Addressing these two concerns required a great deal of time in the early work of both the Ethical Force Expert Advisory Panel on Benefits and the Oversight Body, as the two groups struggled to define the scope of the current project. In the end, important countervailing arguments to these concerns were raised and supported by a majority of the Ethical Force Oversight Body. First, if fairness in benefits design and administration could not be addressed until all outstanding large-scale access issues were resolved and all covered populations were well defined and stable, then it is possible that no progress could ever be made. Second, even health care systems in which every individual has access to health insurance coverage have been pressed to develop fair systems for designing and administering benefits within these systems. Third, some experts suggested that establishing fair processes for benefits design and administration within defined populations might be a precondition for establishing universal health care coverage; that is, one cannot expect Americans to accept any plan for universal coverage that does not first include a reliable and fair system for making coverage decisions. After all, a universal system without clear mechanisms for making coverage decisions would have an undefined, but presumably very large, price tag.^{35, 86}

2. Might Work in This Domain Be Misused?

Having addressed whether to consider benefits design and administration separately from large-scale access to insurance issues, Ethical Force then turned to another, and equally profound, challenge to work in this area. In brief, this was the risk that this work might be especially prone to being subverted or otherwise misused. The second part of this appendix summarizes these concerns.

First, the Expert Advisory Panel and the Oversight Body struggled with the fact that recommendations to improve fairness in benefits design processes might be skirted or “gamed.” After all, organizations that intend to fulfill the letter but not the spirit of any set of recommendations can generally find a way to do so; recommendations to improve the fairness of coverage decisions are no exception. In this regard, it is important at the outset to recognize that no set of expectations or measures can provide an ironclad guarantee of fairness. The relevant question is whether laying out expectations might improve or worsen the current situation.

Second, several experts in our group insisted that the primary, if not sole, factor involved in benefits design decisions today is the cost of providing the benefit. Moreover, they argued that benefits packages are designed within relationships of power that are highly unequal. For example, in most cases today there is limited, if any, direct input from

beneficiaries into purchasers’ (eg, employers’) decisions about what health benefits to buy. Given this lack of input, some Oversight Body members insisted that any mention of “ethical” to describe the benefits design process today would be, at best, misleading.

In the words of one participant, “In our current environment, it is not possible to identify and implement ethical standards for benefits design . . . [because the decisions are] driven largely by economic considerations and implemented by the assertion of power. To attempt to justify or excuse behavior so driven as ‘ethical’ is at best an illusion and at worst dishonest.” Further, this participant continued, “Employee participation in situations where employees do not have the power to effectively determine final decisions is a façade . . . Therefore, efforts to give this process and relationship ‘ethical cover’ by . . . setting expectations that have no chance of meaningful implementation is a subterfuge.”

While this member represented a minority viewpoint (many Oversight Body members believe that ethical considerations often do play a role in designing health benefits packages), all Oversight Body members agreed that even if all organizations achieved the ethical expectations listed in this report, it would not eliminate the important influence of other factors, such as power relations and economic pressures, from the design of benefits packages.

Despite these objections, many Oversight Body members argued that the Ethical Force Program™ should not be reluctant to address the ethics of designing health benefits packages. This, they said, would violate the mission and the greatest promise of Ethical Force. According to some participants, resource allocation decisions—of which benefits design is a core component—pose *the* most pressing ethical challenges in health care today and are likely to become even more important in the future. Thus, any effective guidance from Ethical Force in this domain could be of great consequence.

These members further argued that even though any recommendations can be skirted and manipulated to provide a false appearance of compliance, it is still reasonable to hope that organizations and individuals who follow recommendations regarding ethical behavior will be more likely to act in good faith than organizations that intentionally ignore ethical principles that have been well described and justified. In addition, while there is a risk that a purchaser/employer could practice “pseudo-adherence” to Ethical Force recommendations in order to disguise behaviors driven only by bottom line concerns, a majority of the Oversight Body felt that this risk was at least partly offset by the fact that affected employees could use the Ethical Force recommendations to monitor and criticize such an employer. Finally, even in systems where economic factors primarily drive coverage decisions, it is still likely

that some improvements can be made; that is, incrementally more fair processes for designing health benefits could be implemented. And indeed, the process of considering ethics and implementing new processes might even spark subsequent improvements. Thus, whether or not concerns for ethics and fairness govern how most health benefits packages are designed today, it is clearly possible to improve upon current practices. If this can be achieved, then perhaps ethics and fairness will become more important considerations in the future.

In conclusion, the Oversight Body could not reach complete consensus on whether the risk that our work might be subverted and used to justify inherently unethical situations should preclude the program from addressing these issues. But all Ethical Force Oversight Body members recognize that health care systems change, sometimes rapidly. Reflecting this position, in this report Ethical Force has specifically attempted to develop expectations that can apply, in principle, to dramatically altered systems and not just to the existing United States system. Even with this agreement, however, it must be reinforced that one member of the Oversight Body remains deeply uncomfortable with any attempt or claim to address “ethical” issues in benefits design. For this reason, this report does *not* claim to present a guaranteed plan to ensure an “ethical” system for benefits design. Rather, it presents principles to consider that should be included in such a system, and then offers concrete suggestions based on these principles. All Ethical Force Oversight Body members hope that following these suggestions might improve the fairness of benefits design processes.

Appendix D:

Ethical Issues Involved In Making Coverage Decisions: Review of Existing Standards And Norms

Background

Decisions must be made concerning which health services will be covered by insurance plans and which will not. These decisions are necessary to prevent runaway health care costs and prevent the provision of inappropriate services. Yet, as pressures mount to contain costs, tensions are rising between important stakeholders in the health care system.

All too often, patients and practitioners appear to reject the legitimacy of coverage decisions. Recent research demonstrates that physicians and patients commonly feel justified in “gaming” insurance company coverage decisions, suggesting that patients and doctors too often perceive these decisions to be unfair or illegitimate.¹⁹⁻²¹ Further, while many parties play a direct or indirect role in making coverage decisions, there is a risk that some groups are becoming scapegoats for these decisions, while others may be passing the ethical buck by ignoring or downplaying the role(s) that they play. For instance, the important role of purchasers in shaping benefits packages may not be recognized when only insurers and practitioners are seen to implement benefits restrictions.

Our group found that common methods for the design and administration of benefits packages are undesirable for many reasons, and they may contribute to a perceived lack of legitimacy and fairness in these systems. Still, in our review of existing policies and proposals, we discovered widely articulated and agreed-upon standards and policies that provide a solid framework for improvement based on consensus.

The following organizations, individuals, and methods for approaching these issues made important contributions to the framework set forth in the consensus report. These summary statements are based on materials collected and analyzed during 2000 to 2001.

Accrediting Organization Standards:

NCQA: The National Committee for Quality Assurance has standards for making coverage decisions that address community involvement, determinations of “medical necessity and experimental treatment,” conflicts of interest, the use of evidence-based criteria, coverage of emergency services, and the consistency of decision-making processes. In one example concerning community involvement, the NCQA proposed that managed care organizations (MCOs) assess member satisfaction with the utilization review (UR) process every 2 years and address identified areas of dissatisfaction. With regard to medical necessity decisions, the NCQA standards stipulate that MCOs should gather relevant clinical information and confer with treating physicians when determining coverage based on medical necessity. For experimental treatments, the MCO must have a written description of the procedures that guide decisions regarding coverage of new technologies and new uses for existing technologies. The written description should include the variables used as a basis for decisions and a review of information from government and scientific sources. For MCOs that determine coverage using evidence-based criteria, UR decisions should be based on sound clinical evidence and there should be no incentives for reviewers to make inappropriate decisions. Adherence to all of these criteria must be consistent, and this consistency should be assessed yearly. Finally, specific standards apply to emergency services: precertification for emergency services necessary to screen and stabilize members is not allowed where (a) a prudent, reasonable, layperson believed an emergency medical condition existed, or (b) a practitioner or representative of the MCO authorized the service.

JCAHO: The Joint Commission on Accreditation of Healthcare Organizations has standards addressing medical necessity determinations in three chapters of the 1998-2000 manual, *Standards for Health Care Networks*.⁸⁷ These three chapters are *Leadership, Continuum of Care, and Rights, Responsibilities, and Ethics*.

In the *Leadership* chapter, standards specify the responsibilities of the network’s leaders to ensure that medical necessity determinations are made appropriately. Leaders are required to ensure compliance with applicable law and regulation. They are also responsible for developing and implementing a code of ethical business and professional behavior, which is intended to create a culture that emphasizes ethical behavior and protects basic human rights and dignity. Finally, network leaders are required to approve, in writing, the network’s scope of services, including those provided by contract or agreement. The *Continuum of Care* chapter specifies that health care services provided to network members are to be appropriate to their assessed needs, as determined

by the member’s sociocultural characteristics and in accordance with the network’s mission and contractual obligations. Finally, in the *Rights, Responsibilities, and Ethics* chapter, standards require that the network establish methods for resolving disagreements between the network and the member or designated decision-makers regarding care or treatment decisions. The network’s methods should include:

- Providing members with a description of the treatment and authorization process;
- Identifying individuals who make determinations about admission, care, and transition to another care setting when disagreements arise between the network and the member;
- Providing members with information as to whether, and under what circumstances, investigational procedures are available and/or covered by the network;
- Informing members in a timely manner that a request to authorize treatment has been denied;
- Informing members of the basis and reasons for adverse decisions;
- Informing members of the review criteria used to make the determination;
- Informing members about how to seek appeals of adverse decisions;
- Defining the time frame in which members can anticipate a response to an appeal;
- Ensuring that time frames for appeals are appropriate to the urgency of the member’s health care needs;
- Informing members about further steps available when disagreements cannot be resolved through the treatment authorization process, such as grievance, arbitration, and legal processes.

AAHCC/URAC: American Accreditation Health Care Commission (formerly URAC) standards require that health plan members play an active role in the process of determining their care and treatment. Plans must define appropriate care and make coverage decisions based on medical necessity. Networks must develop mechanisms to record, examine, and address all member complaints, and maintain these documents for each specific network service area in an accessible and secure location. A formal patient grievance procedure with two levels of review is required to provide periodic reports to management summarizing all of the information from the complaints, and the reports should be available to all members.

These efforts by accrediting organizations are important. They confirm that coverage design and administration processes are appropriate targets for performance

measurement in hospitals and health plans. Yet the reach of these organizations is necessarily limited because they can address only the responsibilities of those health care providers they accredit. They cannot directly address, for example, the important roles of purchasers and others in making health benefits coverage decisions.

Some “Whole System” Approaches

Some approaches to improving coverage decisions come from analyses of how entire health care systems function. These approaches aim to improve coverage decisions by making recommendations for how the whole system should work, looking beyond resource allocation and focusing on fundamental goals for entire health care systems, or providing guidance to specific parties, such as physicians, for how they should act within these systems.

Benchmarks of Fairness

Building on *A Theory of Justice* by John Rawls, three scholars—a philosopher, a sociologist, and an economist—developed a set of “benchmarks of fairness” for health care systems.⁸⁸ The authors argue that because disabilities and diseases can compromise the ability to partake in life’s opportunities, fair access to good and effective health care is an important feature of a society that believes in formal and fair “equality of opportunity.” America is such a society, according to these authors, as demonstrated by the Civil Rights Act and the Americans with Disabilities Act (though they note that it could do better in providing a fair health care system by these criteria). In addition, however, the “benchmarks” have recently been revised for use in a variety of countries, including some that might not agree to the underlying philosophical premise.⁸⁹ The current benchmarks of fairness include, for example, “democratic accountability,” “administrative efficiency,” and “patient and provider autonomy.” Interestingly, high scores in the “benchmark” system need not entail governmental or socialist arrangements. In fact, many countries score well on the benchmarks of fairness using private insurers and private physicians.

WHO Framework: Stewardship Over Fair, Good and Responsive Health Care

A team at the World Health Organization (WHO) has been developing a framework for gauging how well different nations maximize the health of their people and distribute services among their populations. This work resulted in the *World Health Report 2000*.⁹⁰ At the center of the framework is the concept of governmental stewardship: “the careful and responsible management of the well-being of the

population—stewardship—is the very essence of government.” Stewardship in health care (for governments) involves three key functions: (1) assuring a level playing field for all parties, (2) setting and implementing fair rules for the financing and operation of the system, and (3) making sure the system is responsive to people’s needs. For instance, WHO calculated criteria estimating how much different countries should achieve based on how much they spend on health care and assuming they could attain benchmarks of efficiency and equity—that is, assuming good stewardship of available resources. By these criteria, the tremendous amount spent in the United States on health care was not enough to counterbalance the inefficiency and inequities of our health system. Compared to other countries, the United States system ranked 72nd in the world on this measure, well below other affluent and even behind many significantly less affluent countries. Thus, according to the Report, the United States receives poor value for its money. By these measures, the United States ranked 24th on overall level of health, and 32nd on health fairness. On fairness of financing, the United States ranked 54th. Overall, these rankings place the US health care system in 37th place and last among the more affluent and developed nations.

The Veterans Health Administration: Equitable Decisions About Limited Funds

The bioethics committee of the Veterans Health Administration (VHA) has developed principles and procedures for how to equitably distribute the VHA’s limited resources.⁹¹ Since the VHA is a national health care system that treats an unusually sick and disabled population on a fixed budget, it is more acutely affected by all the issues that employers, unions, insurers, and health plans must face. The principles they have developed may be divided into those regarding (1) fair procedures and (2) fair coverage.

VHA Rules for Fair Procedures

- Decisions should include representatives from all interested and affected parties.
- Procedures for decisions should foster participation and be explicit, public, and accessible.
- Mechanisms should be in place to respond to special burdens or needs.
- Coverage policies and procedures should be revised frequently.

VHA Rules for Fair Coverage

- Coverage decisions should be based on the overall needs of the entire population.

- Patients with comparable needs should be treated equally.
- Savings (if any) should be used to benefit the population.
- New treatments should be covered only after proven to be more cost-effective than existing treatments.
- With regard to “unproven treatments,” coverage should be based first on the degree of expected efficacy, second on relevance for diseases of greater burden, third on consistency with accepted national practices, and fourth on consistency with accepted local practices.

The Oregon Health Plan: Oregon’s Basic Health Services Act

In the late 1980’s, political and health care leaders in the state of Oregon argued that it was unjust for Medicaid to exclude certain categories of the poor from services, and that the state should rather cover a smaller number of services that could be provided to all of the poor.⁹² The question was: which services should be covered? The state undertook a lengthy public process to determine which services should be given higher and lower priority, resulting in a ranked list of all potential services and procedures, with the cutoff point for funding to be determined by the size of the state’s health care budget. The package of covered services would be offered as a managed care plan for the state’s Medicaid enrollees and called the Oregon Health Plan (OHP).⁹³ The procedures used to create the list emphasized widespread public participation, such as a telephone survey of state residents and a large number of local, focus-group type “community meetings.”⁹³ Although, in fact, most participants in the community meetings were among the more affluent and more educated, and the telephone survey was similarly criticized for missing those without phone service, these tangible outreach efforts provided a considerable degree of legitimacy for the Oregon Health Services Commission to develop the list.^{94, 95} In addition, the state government contracted to perform a cost-effectiveness analysis of the items on the list, though in the end these data were not explicitly used to prioritize the items.^{71, 95}

The OHP has now been in place for more than a decade and the success of the program is generally acknowledged, though not without reservations.⁹⁴ For instance, it has been noted that the list of covered services is quite comprehensive (even more so than the Medicaid package in place prior to the OHP). Therefore, although the list was ranked, little in the way of “rationing” was accomplished by the public prioritization process of developing the OHP.⁹⁶

Professional Association Policies

Professional associations, such as the *American Medical Association (AMA)*, have policies that specifically address their members’ roles in resource allocation processes. In perhaps the most prominent and comprehensive example, the *AMA’s Council on Ethical and Judicial Affairs* has stated:

“A physician has a duty to do all that he or she can for the benefit of the individual patient. Policies for allocating limited resources have the potential to limit the ability of physicians to fulfill this obligation to patients. Physicians have a responsibility to participate and to contribute their professional expertise in order to safeguard the interests of patients in decisions made at the societal level regarding the allocation or rationing of health resources.

[Ethically acceptable considerations in allocation decisions include] likelihood of benefit, urgency of need, change in quality of life, duration of benefit, and, in some cases, the amount of resources required for successful treatment. In general, only very substantial differences among patients are ethically relevant; the greater the disparities, the more justified the use of these criteria becomes. In making quality of life judgments, patients should first be prioritized so that death or extremely poor outcomes are avoided; then, patients should be prioritized according to change in quality of life, but only when there are very substantial differences among patients. Nonmedical criteria, such as ability to pay, age, social worth, perceived obstacles to treatment, patient contribution to illness, or past use of resources should not be considered.

Allocation decisions should respect the individuality of patients and the particulars of individual cases as much as possible. When very substantial differences do not exist among potential recipients of treatment on the basis of the appropriate criteria defined above, a “first-come-first-served” approach or some other equal opportunity mechanism should be employed to make final allocation decisions. Though there are several ethically acceptable strategies for implementing these criteria, no single strategy is ethically mandated. Acceptable approaches include a three-tiered system, a minimal threshold approach, and a weighted formula. Decision-making mechanisms should be objective, flexible, and consistent to ensure that all patients are treated equally.

The treating physician must remain a patient advocate and therefore should not make allocation decisions. Patients denied access to resources

have the right to be informed of the reasoning behind the decision. The allocation procedures of institutions controlling scarce resources should be disclosed to the public as well as subject to regular peer review from the medical profession."⁹⁷

State and specialty professional associations have also addressed these issues, often expressing frustration at the current American health care system. As one example, *The American College of Physicians-American Society of Internal Medicine Ethics Manual* states that:

"...considerations of justice inform the physician's role as citizen and clinical decisions about resource allocation. The principle of distributive justice requires that we seek to equitably distribute the opportunities afforded by health care. How to accomplish this distribution is the focus of intense debate. More than ever, concerns about justice challenge the traditional role of physician as patient advocate.

The environment for the delivery of health care is changing. Sites of care are shifting and managed care continues to grow, yet the US health care system does not serve all of its citizens well and major reform is needed. It is unclear how to reform the system to achieve that goal. Health care financing is a serious concern, and society's values will be tested in decisions about resource allocation."⁹⁸

Using Cost-Effectiveness Assessments in Prioritizing Coverage

In contrast to "whole system" approaches, some writers and policy makers have explored the use of specific methods, such as cost-effectiveness analyses, as tools for making coverage decisions. Research from the Ethical Force Program™ suggests that cost-effectiveness is often an important criterion in making coverage decisions. An analysis of actual health plan, medical group practice, and professional society ethics policies revealed that the cost-effectiveness of proposed interventions was often the *only* criterion regarding resource allocation decisions that was explicitly mentioned. (It should be noted that we examined only organizations' ethics policies. Additional policies on coverage decisions might exist, but they were not considered by the organizations to be ethics-related and so were not examined.)⁹⁹

A leading proponent of the use of cost-effectiveness analyses in health coverage decisions is Dr. David Eddy. Eddy focuses his discussions both on assessing the cost-effectiveness of procedures that are already covered by plans, as well as assessing evidence that new treatments will be worthwhile.^{15, 100, 101} In order for a new intervention to be covered, he suggests, it should be more beneficial than the harmful effects that could result and

better than the most cost-effective method available. In cases where the treatment is experimental, and there is insufficient evidence to predict its effects on health outcomes, he proposes that it be labeled "investigational," and offered only in a clinical trial setting. In 1996, at a workshop led by Dr. Eddy and sponsored by the National Institute for Health Care Management, a group of medical directors and legal counsel agreed upon several specific benefits coverage criteria for health plans, including:

- (a) The intervention is used for a medical condition;
- (b) There is sufficient evidence to draw conclusions about the intervention's effects on health outcomes;
- (c) The evidence demonstrates that the intervention can be expected to produce its intended effects;
- (d) Expected beneficial effects outweigh expected harmful ones;
- (e) The intervention is the most cost-effective method available to address the medical condition.¹⁰⁰

Dr. Stanley Reiser has proposed a variant of the use of cost-effectiveness in making coverage decisions. Reiser has promoted the concept of "crossover therapies" in addition to experimental and standard therapies.¹⁰² In particular, as new uses for standard therapies are discovered and explored, use may fluctuate between classification as experimental and standard. Those treatments that seem to benefit patients but that do not have enough evidence to prove that they do so would be called "crossover therapies," and their use would be governed by national, perhaps governmental, organizations.

A medical ethicist, Dr. Peter Singer, has proposed another variation of how effectiveness data might be used in making benefits coverage decisions. He explains and reviews two related decision-making criteria: evidence based medicine (EBM) and cost-effectiveness analysis (CEA).⁶⁸ He defines EBM as "the conscientious and judicious use of current best evidence from clinical care research in the management of individual patients" and CEA as "a method for evaluating the health outcomes and resource costs of health interventions [whose] central function is to show the relative value of alternative interventions for improving health." Singer suggests "transcending" EBM and CEA by creating an interdisciplinary approach to decision making that incorporates philosophy, law, political science, economics, and clinical epidemiology into a process that will be perceived as fair by stakeholders in health communities. For example, he suggests that, in addition to EBM and CEA as criteria, extreme need (defined as a situation in which there is "an impending risk for death or severe harm that could be reduced by. . . treatment, in the absence of other treatment options") coupled with some evidence of benefit should merit benefits coverage.

Dr. Erik Nord has recently suggested a methodology in a similar vein to Singer's, which he calls cost-*value* analysis, to overcome some of the objections leveled against standard CEA.⁶⁹ He proposes that societal and ethical values can be incorporated numerically into cost-effectiveness studies, and indeed *must be* considered in order to make CEA useful and to make the implications of CEA acceptable. For example, his methodology would give more weight to caring for severely ill and disabled people compared to conventional CEA.

In examining proposals, such as those of Singer, Nord, and Eddy, to expand and tailor the use of CEA in making benefits decisions, it is critical to recognize that conducting any sort of "advanced CEA" to develop a comprehensive assessment of a wide range of services and potential services would require clear and reproducible methodology and a massive investment. In this regard, several programs have made especially significant progress in developing standardized methods for CEA and in performing assessments of a wide range of new and emerging technologies.

US Public Health Service Expert Panel on Cost- Effectiveness in Health and Medicine

Following more than 2 years of in-depth research and deliberation, a panel of economists, ethicists, psychometricians, and clinicians appointed by the US Public Health Service developed a model system for performing and reporting the results of cost-effectiveness analyses in health and medicine.⁶⁵ The panel's recommendations for standardization were an important step towards developing ways to compare alternative methods of improving health, based on their costs and outcomes, for health policy decision- making. Among the panel's most important recommendations was that CEA should generally include the use of "reference case" assumptions and methods, which would allow cost-effectiveness analyses performed by different organizations for different purposes to be usefully compared to each other. The reference case is to be based on a "societal perspective," so that costs to all relevant parties would be included in the calculation of the cost of an intervention. This means, for example, that the costs of taking time off from work for health care visits should be incorporated into the cost of the visit for purposes of the reference case analysis. Moreover, the timeline captured in the CEA should be long enough to capture "all relevant future effects of a health care intervention."⁶⁵

The Technology Evaluation Program (TEC) of the Blue Cross and Blue Shield System

In 1985 the Blue Cross and Blue Shield Association established its TEC to assist member plans in evaluating new medical technologies. The initial goals of the TEC included the promotion and purchase of excellent health care for members of BCBSA plans, "allocating premium dollars to services of known benefit," and "limiting payment for new technologies to those of demonstrated effectiveness." Since its founding, the TEC has collaborated with many organizations outside of BCBSA, and it now serves as a resource for many clients, federal and private health plans, and pharmaceutical and device manufacturers. The TEC uses scientific evidence to evaluate new technologies for effectiveness, but the TEC does not address issues of cost. The TEC's Medical Advisory Panel, which includes members from both within and outside of BCBSA plans, uses five criteria in its evaluations. The criteria are: (1) the technology must have final approval from the appropriate government regulatory body; (2) the scientific evidence must permit conclusions concerning the effect of the technology on health outcomes; (3) the technology must improve net health outcomes; (4) the technology must be as beneficial as any established alternatives; and (5) the improvement must be attainable outside the investigational setting. Recommendations based on these criteria as to whether a technology is beneficial are of an advisory nature for health plans and other TEC clients, though many health plans consider new technologies that do not meet the TEC criteria to be investigational and ineligible for coverage.

Contributions from Ethics and Political Philosophy

The field of political philosophy has generated some important ideas regarding workable systems of accountability for resource allocation in health care. Ezekiel Emanuel, a physician and political philosopher, has suggested four procedural principles to guide the allocation of resources within managed care health plans. The principles for allocation are: (1) improving health should be the goal; (2) patients and members should be informed; (3) patients and members should have the opportunity to consent; and (4) conflicts of interest should be minimized.¹⁶ In related work, Emanuel has called for publicizing resource allocation decisions and the reasons behind them, as well as for a fair appeals process.¹⁰³ Political philosophers Guttman and Thompson¹⁸ similarly call for the use of four standards to assess health care resource allocation decisions. Namely, these decisions should be accessible, moral, respectful, and revisable. Also addressing accountability, Daniels and Sabin have proposed that society should ensure *accountability for reasonableness* in health care benefits

decisions.⁵⁸ In Daniels and Sabin's terms, rationales offered for coverage decisions must meet "fairness standards." Thus, "accountability for reasonableness" requires decision makers to publicly offer rationales for resource allocation decisions that "fair-minded" people can agree are relevant to assuring appropriate patient care under necessary resource constraints. In their view, this process entails meeting four conditions: (1) *Publicity*: coverage decisions and rationales for new technologies and other limit-setting decisions must be publicly accessible; (2) *Relevance*: rationales must be founded on evidence, reasons, and principles that all fair-minded parties can agree upon in meeting the diverse needs of a covered population under necessary resource constraints; (3) *Appeals*: a mechanism to challenge limit-setting decisions and the opportunity for reform in light of new evidence and arguments should exist; and (4) *Enforcement*: voluntary or public regulation of the benefits determination process exists to ensure that the first three conditions are met.

Stratified model of accountability

Ezekiel and Linda Emanuel have developed a "stratified model" of *professional, political, and economic accountabilities* as a way to evaluate health care decision-making, using three different sources of ethical guidance.⁶ The Emanuels argue that because health care includes so many different types of relationships, no single system of accountability can or should be applied across the board. Where there are different sets of mutually responsible parties, there may be separate sets of criteria for expectations regarding accountability in those various relationships, as well as distinct mechanisms to ensure accountability. Rather than a single umbrella system over all aspects of decision-making in health care, they advocate a multilayered model. Under this approach clinician-patient interactions should be guided by *professional* accountability, intraplan relations (such as between clinicians and managers) by *political* accountability, and interplan relations and health care relations between and among investors, government, employers, and others, by either political or *economic* accountability or both.⁶

Conclusion

In addition to the work summarized above, several recent books have addressed these issues.^{14, 104-106} In these books, as in the summarized material above, the reader will note that several common themes consistently appear, despite the wide range of scholars and organizations involved. For instance, given the importance of community participation and transparency in decision-making processes, the importance of reasonable appeals processes, the appropriate consideration of cost—to name a few—it should not be surprising that these areas of commonality form the foundation of the framework for improving fairness in the health care system that is presented in this consensus report. What was noted in the Introduction should now be quite clear; few of the ideas in this report are new. The report, in fact, represents a collection and coordination of excellent work already performed. If this report is helpful, it is because it builds upon the solid foundation laid by others.

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