

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.