MINNESOTA MDH DEPARTMENT OF HEALTH

Protecting, maintaining and improving the health of all Minnesotans

January 15, 2010

The Honorable Linda Berglin
Chair, Health and Human Services
Budget Division
Minnesota Senate
Room 309, State Capitol
75 Rev. Dr. Martin Luther King Jr. Blvd.
Saint Paul, MN 55155-1606

Dear Senator Berglin:

The 2008 Legislature required the Minnesota Department of Health (MDH) to convene a work group to make recommendations on the design of an "essential benefit set" that provides coverage for a broad range of services and technologies, is based on scientific evidence that the services and technologies are clinically effective and cost-effective, and provides lower enrollee cost sharing for services and technologies that have been determined to be cost-effective (Minnesota Statutes, Section 62U.08). The Essential Benefit Set Work Group's recommendations with regard to the design of this health insurance benefit set are described in the enclosed report.

The law requiring MDH to convene the Essential Benefit Set Work Group relates to two important policy goals that were discussed by the Minnesota Legislature in 2008:

- The first goal was to ensure adequacy of health insurance coverage. Specifically, there are concerns that the trend toward higher enrollee cost-sharing in private health insurance markets may have the unintended effect of patients' delaying or avoiding necessary care, which could in turn result in worse health outcomes and higher costs.

- The second goal was to establish consumer incentives that encourage more (or more consistent) use of services and technologies that have been demonstrated to be clinically effective and/or cost-effective, and less use of ineffective services or services that are not cost-effective.

With regard to adequacy of coverage, there are clear tradeoffs between comprehensiveness and affordability of health insurance coverage:

- The more services that are built into the benefit set, or the more services that have first-dollar coverage or very low cost sharing, the more expensive the premium for health insurance coverage will be. In addition, lower cost sharing leads to more use of services (both effective and ineffective services), and greater potential for harm from exposure to unnecessary care. The work group concluded that while it is likely desirable to provide

coverage for highly effective services on a first-dollar basis, cost sharing should continue to be a feature of health insurance coverage for other services.

- Work group members pointed out that not everyone wants or needs first-dollar insurance coverage, and that consumers should not be prevented from making their own decisions about the level of financial protection to purchase.

- The work group was reluctant to specify a benefit set that requires a more comprehensive set of services than is typically covered by private insurance plans today, due to concerns about added cost. The work group also did not identify major gaps in existing coverage that it would recommend addressing through additions to a typical Minnesota insurance benefit set.

- For consumers who have insurance but still cannot access appropriate care because of cost barriers, the work group recommended that policy makers address this problem through the use of targeted subsidies, rather than through benefit set requirements that apply to the entire market.

For several reasons, the work group's report does not recommend a specific list of services that should be incorporated into an essential benefit set:

- One of these reasons, mentioned above, is that the work group did not find major gaps in existing private insurance benefit sets – in general, work group members concluded that health plans' decisions about inclusion of services in benefit sets have appropriately incorporated coverage for services that have been demonstrated to be clinically effective. For example, work group members noted that health plans in Minnesota generally cover preventive services in a manner consistent with Institute for Clinical Systems Improvement (ICSI) guidelines for appropriate delivery of these services.

- Cost effectiveness, defined by the work group as the least costly treatment that achieves the same results as other available treatments, is more difficult to incorporate directly into a benefit design since a decision about which treatment option is likely to be most cost-effective may depend on the situation of an individual patient.

- One additional reason why the work group chose not to use a "list" approach to making its recommendations is the lack of systematic evidence about the relative effectiveness of many health care services and treatments that are commonly provided. Current standards for approval of treatments consider safety and efficacy, but usually not comparative effectiveness or cost effectiveness. Although significant progress is beginning to be made, the state of the art of research in this area is not yet advanced enough to support the design of a robust value-based health insurance benefit set.

- Work group members concluded that a list-based approach to designing an evidence-based benefit set would make benefit sets more difficult for consumers to understand if

coverage for a particular service depends on their specific circumstances. In addition, such an approach would be more complex for health plans to administer.

- Finally, work group members noted that other strategies to encourage more consistent delivery of evidence-based care (such as tiered provider networks, preferred providers for the treatment of specific conditions, and health care payment reforms) likely have greater potential to improve the delivery of clinically effective and cost-effective care.

At times, the work group struggled with the lack of clarity in the law about the intended use of the essential benefit set. For example, it is unclear whether the essential benefit set might be used to establish a minimum level of insurance coverage for all Minnesotans with private insurance, whether it might alternatively serve as a benchmark for determining eligibility for subsidies of private insurance premiums, or whether it might be used in some other way. The work group's recommendations assume that the essential benefit set would be a private insurance product that is offered alongside existing products in the private health insurance market in Minnesota, but their report also offers additional recommendations for the use of the essential benefit set in an environment in which individuals are mandated to purchase health insurance.

As you know, significant health reforms are now being debated at the national level. Among these are changes that would require most individuals to acquire and maintain health insurance coverage, and that would establish a minimum standard for what level of coverage meets this requirement. The overall standard for determining adequacy of coverage would incorporate both an assessment of the actuarial value of a health plan (which is the average share of covered services paid for by the health plan for a given population), as well as coverage for a specific list of services to be defined at a later date. The work group report acknowledges that these proposals, if enacted, may have impacts on Minnesota beyond the work group recommendations.

Questions and comments on the Essential Benefit Set Work Group's process or its report may be directed to the Health Economics Program at (651) 201-3560.

Sincerely,

Sanne Magnan, M.D., Ph.D.
Commissioner
P.O. Box 64975
St. Paul, Minnesota 55164-0975

Identical letter sent to Senator Michelle Fischbach, Senator Paul Koering, Senator John Marty, Representative Jim Abeler, Representative Matt Dean, Representative Thomas Huntley, and Representative Paul Thissen

Essential Benefit Set Work Group

RECOMMENDATIONS REPORT

November 2009

Prepared by:

CIRDAN
Health Systems and Consulting

Submitted to:

MINNESOTA MDH DEPARTMENT OF HEALTH

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Executive Summary

WORK GROUP CHARGE

The Commissioner of Health was charged by Minnesota Statute 62U.08 to convene a Work Group to design an Essential Benefit Set (EBS). The primary objective of the EBS is to encourage greater use of effective health care services and less use of ineffective or low-value services. The EBS is specifically required to provide coverage for a broad range of services and technologies that are based on scientific evidence of clinical- and cost-effectiveness, and provide lower enrollee cost sharing for services and technologies that have been determined to be cost-effective. The Work Group spent substantial time considering the scope of its charge and concluded that the primary goals of the EBS should be: (1) to protect individuals from catastrophic financial loss; (2) to optimize health status and outcomes, including both individual and population health, through the use of clinically effective, cost-effective, evidence-based health care services; and (3) to ensure access to appropriate care by minimizing cash flow challenges.

CONCLUSIONS

The Work Group reached the following conclusions related to the current market for privately purchased health insurance and the need for and role of its EBS recommendations:

- Government definition of an EBS carries the premise that the market has somehow produced the wrong answer. Specifying an EBS should be accompanied by a clear explanation of exactly what went wrong in the market, why it went wrong, and why specifying benefits is the best solution to whatever the problem is thought to be.

- Private market coverage of health care services is generally (although not always) sufficient to encompass services that are necessary, clinically effective, and cost-effective. However, benefits are generally structured so broadly that they include services that are both effective and ineffective. That is, if a service can be effective in any situation, it may be covered in all situations (including when not effective).

- The current state of health care services delivery presents significant opportunity to improve outcomes and reduce costs both through increased use of effective services and, of equal importance, decreased use of ineffective services. While changes in benefit design may play a role, other strategies such as provider network design and payment reforms are also needed to more fully realize this opportunities for improved system performance.

- The determination of whether services have been provided in a clinically- and cost-effective manner is, in most but not all cases, too complex to evaluate and administer through standard covered service descriptions as expressed in health insurance product language, or through standard claims adjudication processes.

RECOMMENDATIONS

The Work Group recommendations apply to the current private insurance market, with additional recommendations for a mandated / universal coverage scenario:

1. Rather than developing a static list of covered services, an "Essential Benefit Set Certified Product" category should be established and defined as a health insurance product that provides coverage based on scientific study and evidence of clinical- and cost-effectiveness, as described in the detailed recommendations. EBS Certified Products should provide a level of coverage that incorporates and balances comprehensiveness, affordability and accessibility.

2. EBS Certified Products should cover evidence-based clinical services, and exclude categories of services commonly excluded from standard health insurance policies. EBS Certified Products should provide distinct coverage levels for different services according to their status with respect to evidence-based clinical- and cost-effectiveness, and related benefit administration categories, including:
   a. *Higher than standard coverage* should be provided for services determined to be highly clinically- and cost-effective, including highly recommended and research-based: (1) preventive services that can be identified on the basis of health care claim-based information, and (2) other services that can be identified through specific programs, networks, or other methods that achieve effective outcomes. Where multiple evidence-based options are available that are comparable in effectiveness, coverage should accommodate different options and preferences.
   b. *Standard or lower coverage* (compared to "a") should be permitted for services: (1) with limited or no evidentiary basis, (2) new services with premature evidence, or (3) services where it is not practical to apply evidence-based standards to the benefit design.
   c. *Coverage should not be required* for services that research has shown to be: (1) clinically ineffective or harmful, or (2) not cost-effective. The terms of coverage for services currently defined as "mandated benefits" should be the same as for any other services and based on the same scientific research standards.

3. A panel of health care system stakeholders should be appointed to provide ongoing oversight and maintenance of the EBS, with technical support from qualified research and analysis organizations already engaged in similar activities. The panel should ensure that the evidence-based EBS criteria and principles are maintained and advanced, and that a buffer is provided from political pressures. A state agency should evaluate whether specific health insurance products meet the qualifications to be "EBS Certified."

4. Actual or potential market barriers to the feasibility and success of EBS Certified Products should be addressed through:
   a. Liability protections for specific activities related to EBS Certified status.
   b. Targeted health plan premium risk adjustment and price differential corrections.
   c. EBS criteria to promote long-term "return on investment" for population health.

Work Group Charge and Activities

The Commissioner of Health was charged by Minnesota Statute 62U.08 to convene a Work Group to design an Essential Benefit Set (EBS). The primary objective of the EBS is to encourage greater use of effective health care services and less use of ineffective or low-value services. The EBS is specifically required to:

- Provide coverage for a broad range of services and technologies;
- Be based on scientific evidence that the services and technologies are clinically- and cost-effective; and
- Provide lower enrollee cost sharing for services and technologies that have been determined to be cost-effective.

As further clarification of the Work Group's charge and to provide additional focus for Work Group discussions, the Minnesota Department of Health (MDH) asked the work group to consider the following issues:

- What health care services should be included in the EBS?
- Are there services that are not typically covered by private insurance that should be included?
- Are there services that are typically covered that should be excluded?
- What structure of enrollee cost sharing will optimize the use of effective care? For example, should deductibles or other cost sharing requirements be waived for services for managing chronic disease or that contain long-term health care cost growth?

Copies of the Minnesota Statute 62U.08 and the MDH EBS Work Group Charge are included as Appendix E.

The lead consultant engaged for the project was Cirdan Health Systems and Consulting (Cirdan), with significant additional support from its subcontractor, the Minnesota Center for Health Care Ethics (MCHCE). Cirdan staff led presentations and research materials most closely related to insurance costs, benefit design, market operations, and practical examples or models of value-based coverage. MCHCE staff led group facilitation, structured decision-making, and presentations and research materials most closely related to health services and health policy research.

WORK GROUP MEMBERSHIP

As directed by the statute, the membership of the Essential Benefit Set Work Group included highly qualified representatives from health care providers, health plans, state agencies, and employers. The makeup provided a mixture of expertise in such areas as standards for evidence-based care, benefit design and development, actuarial analysis, and analysis of the cost impact of coverage of specified benefits. Work Group members included:

- Bruce Anderson, Benefits Manager, Employee Insurance Division, Minnesota Management & Budget
- Susan Castellano, Manager, Maternal and Child Health Assurance, Minnesota Department of Human Services
- Bryan Dowd, Ph.D., Mayo Professor, University of Minnesota, Division of Health Policy & Management
- Amy Gilbert, MD, MPH, Public Health and Preventive Medicine Committee, Minnesota Medical Association
- Patrick Herson, MD, VP, Major Accounts & Consumer Strategy, Blue Cross Blue Shield of Minnesota, on behalf of the Institute for Clinical Systems Improvement
- Thomas Hesse, VP, Government Affairs, Minnesota Chamber of Commerce
- Roger Kathol, M.D., President, Cartesian Solutions, Inc.
- Steve Larson, Public Policy Director, The Arc of Minnesota
- Mary Maertens, Chief Executive Officer, Avera Marshall Regional Medical Center
- Nancy Nelson, VP & Chief Actuary, Blue Cross and Blue Shield of MN
- Julia Philips, Director, Actuarial & Regulatory Policy Analysis, Minnesota Department of Commerce
- Robert Stevens, President, Ridgeview Medical Center
- Rich Sykora, VP & General Manager, Medica
- N. Marcus Thygeson, MD, VP & Medical Director, Consumer Health Solutions, HealthPartners
- Diana Williams, Client Consultant, The KNW Group

BACKGROUND PAPER

To provide a framework for evaluating EBS coverage options and to provide a synthesis of relevant research, Cirdan prepared and distributed a Background Paper prior to the Work Group's first meeting. The paper included examples of similar efforts that sought to define an essential benefit set and/or to apply scientific evidence to insurance design.

With respect to the charge of using cost sharing mechanisms to encourage use of clinically- and cost-effective services, the Background Paper identified resources on the closely related topic of Value-Based Insurance Design (VBID), including:

- Specific benefit design options for an EBS;
- Specific conditions that have typically been considered for VBID or other Evidence-Based Medicine (EBM) insurance designs;
- Practical implementation and regulatory considerations;
- Early VBID experience from various companies, employers, states, and countries; and

- Actuarial considerations for designing and pricing the EBS.

The Background Paper was informed by interviews with local and national researchers including:

- The Institute for Clinical Systems Improvement (ICSI);
- The University of Minnesota, Division of Health Services Research and Policy;
- The Chair of the American Academy of Actuaries, Health Care Quality Work Group; and
- Leading Minnesota health plans, health care providers, state agency staff, and advocates serving on the Work Group.

The paper also incorporated a review of available research identified in connection with the Legislative Commission on Health Care Access, including:

- The Center for Evidence-Based Policy at Oregon Health Sciences University
- The State of Washington Health Technology Assessment Program
- The State of Oregon's Prioritized List
- The National Institute for Health and Clinical Excellence in the United Kingdom

Finally, an extensive literature review was compiled from academic and practice-oriented sources including health policy, managed care, public health, health care ethics, and insurance benefit design and cost analysis. The Background Paper's "Resources" section included a summary of these sources for Work Group members who were interested in additional background. The electronic version of the paper included links to these articles and websites. During the course of the Work Group's proceedings, additional articles were submitted by group members. These additions were included in an addendum to the Resources section and were distributed to the group. A copy of the research paper is available on MDH's website, located at http://www.health.state.mn.us/healthreform/essential/.

WORK GROUP MEETINGS

The Work Group held a series of seven half-day meetings during September and October of 2009. All Work Group meetings were open to observation by the public. Copies of agendas, handouts, and minutes are available for review on MDH's website at the link provided above. The meeting schedule was as follows:

Meeting 1, Wednesday, September 9, 2009, from Noon-4 p.m.

Meeting 2, Friday, September 18, 2009, from 10:30 a.m.-2:30 p.m.

Meeting 3, Thursday, September 24, 2009, from Noon-4 p.m.

Meeting 4, Friday, October 2, 2009, from Noon-4 p.m.

Meeting 5, Thursday, October 8, 2009, from Noon-4 p.m.

Meeting 6, Friday, October 16, 2009, from 8 a.m.-Noon

Meeting 7, Thursday, October 29, 2009, from 9 a.m.-Noon

DISCUSSION DOCUMENTS AND PRESENTATIONS

Given the compressed timeline to complete the work and the high level of experience and understanding brought to the Work Group by its members, limited meeting time was devoted to background education. The primary emphasis of discussion documents was on the technical and policy issues associated with benefit design. To the extent possible, the documents presented issues to the Work Group that were structured as options leading to decisions related to EBS designs. The discussion documents highlighted the implications of various options in terms of the following types of technical, policy, and cost factors:

- Availability of specific and credible clinical, public health, and health services research;
- Administrative feasibility of implementation;
- Feasibility in terms of member understanding, communications, and decision tools; and
- Market positioning and competitiveness issues.

Discussion documents were informed by the fact that the type of product envisioned by the project charge does not yet fully exist in the market. While elements of value-based or evidence-based models are beginning to emerge (including the example described on pages 23-26), a comprehensive insurance product based on these principles does not yet exist based on the research. In this context, meeting agendas, presentations, and hand-outs were structured to progress quickly through the benefit design questions, to identify obstacles, and then to identify solutions to overcome those obstacles.

The Work Group heard a presentation from the Institute for Clinical Systems Improvement (ICSI). ICSI's Director of Clinical Products & Systems Improvement, Kathy Cummings, RN, MA, presented an overview of ICSI, EBM guidelines, their process for developing and maintaining guidelines, and examples of guidelines in use in their DIAMOND Project targeting depression. Examples of additional topics and issues addressed by the Work Group and in discussion documents include:

- Discussions of the project scope and uses of the EBS.
- Background assumptions, goals, and principles for the EBS.
- A model for coverage decision making and a recommended framework.
- An overview of Medicaid, small group, and individual benefit sets.
- Condition / service needs to cover in an EBS.
- Treatment of Minnesota's mandated benefits list within the EBS.
- Examples of tools or initiatives currently used by insurers to add value and drive quality.
- An overview of basic design options to incorporate evidence into benefit design.

- Listings of guidelines, the scope covered services, and evidence grading.
- Examples of cost sharing differentials seen in value-based design.
- Options for specific covered services including those recommended by the public.
- Benefit options for specific covered conditions.

Selected discussion documents from Work Group meetings are included in Appendix C.

PUBLIC INPUT

Due to the limited meeting time available, the Work Group chose not to allocate time for public testimony in the agendas. Observers, advocates, and other members of the public were formally invited to submit comments and suggestions for the Work Group's consideration. A summary of that input is included as Appendix D.

The Work Group found the submissions to be of high quality and appreciated the care taken by their authors. The input could be broadly classified into two categories: (1) input advocating for coverage of certain services within the EBS, and (2) input broadly related to either the legislative charge or EBS purpose and goals.

The Work Group considered the first type of input during multiple meetings that touched on covered services. Since the Work Group chose not to take a "list" type approach to covered services (as will be discussed further later in this recommendations report), many of the areas discussed in the public input are not individually addressed in the recommendations that follow. However, the Work Group did note that much of the input advocated in areas that are standard in benefits sets seen today in the private market. Further, the recommendations contained within this report are not expected to dramatically alter that coverage within an EBS, assuming that these services are in fact supported by the strong evidence of clinical- and cost-effectiveness, as advocated for in the public input.

Not all services receiving public input will be included within the EBS, however. This was the result of deliberate consideration of which specific categories of service should be included and which should be excluded, acknowledging the need to balance comprehensiveness with affordability (this topic is also discussed in greater detail later in this report).

Definitions

In the course of its deliberations, the Work Group found it helpful to agree on the definition of several important terms. The following definitions also apply to these terms as used in this report:

Clinically Effective – As used in this report "clinical effectiveness" most simply is a measure of the extent to which a particular service does what it is designed to do. It often is used more generically as an umbrella term to refer to activities which have as their focus the measuring, monitoring, and improving of clinical care. For example, clinical audit, research and development, education and training, continuous quality improvement, care pathways, and evidence-based clinical guidelines could all be encompassed within the definition. In this broader sense, clinical practice is continuously refined in light of emerging evidence of effectiveness, and considers aspects of efficiency and safety from the perspective of the individual patient or community.

With respect to the EBS, the legislation specifically mentions scientifically-based practice standards established by the Institute for Clinical Systems Improvement (ICSI). In addition to ICSI, many other organizations supply evidence-based protocols or guidelines, including the Agency for Healthcare Research and Quality (AHRQ), the Minnesota Evidence-Based Practice Center, and many physician specialty societies. There are sometimes differences of opinion between organizations about best practice standards. The Work Group suggests that two ways to evaluate which set of standards in a particular case may be most appropriate are to consider: (1) which is best supported by the most reliable evidence (i.e., rigorous application of evidence grading criteria discussed below), and (2) which promotes more conservative (i.e., safe and efficient) services before resorting to more aggressive services.

Clinical Services – "Clinical services" includes a broad range of services, procedures, tests, drugs, and technologies directed primarily to the diagnosis and/or treatment of patients to treat, cure, assess, or prevent illness, injury, or disease or related symptoms. Examples include (but are not limited to) inpatient hospital care, outpatient care, prescription drugs, mental health and substance abuse services, and other professional health care services including care coordination by a health care provider.

Comprehensive – Per Minnesota Statute 62U.08, subdivisions 1 and 2, "comprehensive" refers to a broad range of necessary health care services, procedures, diagnostic tests, drugs, and technologies that are scientifically proven to be both clinically effective and cost-effective. The term, as used by the Work Group and the legislation, does *not* specify the level of member cost sharing for services included within the EBS – i.e., the term is not synonymous with first dollar coverage.

Cost Effective – There are two different and distinct definitions of "cost effectiveness" that the Work Group discussed. The first definition is related to a comparison of the costs of treatments for the same medical condition. In this case, if treatment A is relatively equal to or more effective at a cost that is less than treatment B, it is more cost effective. This definition, while it can be complicated due to the complex nature of patient response to treatment and imperfect medical

knowledge, is measurable and quantifiable. Under this definition, the "cost effective" treatment is preferred and the alternative treatment that is more costly or less effective does not receive coverage. A simple example is a benefit design where generic drugs are covered and brand drugs are not in circumstances where the two are chemically identical.

The second definition of cost effectiveness is not a comparison of the costs of two treatments, but instead a comparison of the cost of a treatment against the "hypothetical gain" received by the patient. Under this definition, instead of determining which treatment provides for acceptable outcomes at less cost, the determination is whether to provide treatment or not depending upon a comparison of the cost of the service against some measure of economic or perceived value related to the outcome of the treatment. This definition of cost effectiveness requires a definition of value to apply to the outcome.

Considerable complexities arise when attempting to define value under the second definition. Definitions of value vary among groups in society because they assess costs or value life, improved health outcomes, or other consequences differently. A state legislative body, business leaders, managed care organizations, health care providers, and the pharmaceutical industry may all view an analysis differently than the individual patient and general public because they seek different objectives and may consider impacts over different time horizons.

The Work Group concluded that the first definition of cost effectiveness should be adopted for the primary purpose of the EBS under current market conditions. It was the consensus of the group that sufficient opportunities exist under the first definition for improvement in health outcomes and savings through reduced inefficiencies if excess and ineffective services can be eliminated, and that it was not therefore necessary to adopt the second definition. For a future universal coverage scenario, potential applications of the second definition could be desirable, subject to achieving political consensus on the definition of value, which is beyond the scope of this Work Group's activities. (See recommendations #2a and #11.)

Evidence Based Medicine (EBM) – "Evidence based medicine" refers to the conscientious, explicit, and judicious use of current best-available evidence gained from scientific study to guide decisions about the care of individual patients. EBM seeks to assess the quality of evidence of the risks and benefits of treatments, including lack of treatment. EBM seeks to clarify those parts of medical practice that are in principle subject to scientific methods and to apply these methods to ensure the best possible prediction of outcomes in current medical treatment. In some circumstances, the development of guidelines or protocols is based on clinical consensus where rigorous scientific studies are not available or sufficient. It should also be noted that many aspects of medical care depend on individual value judgments, which may not be subject to scientific methods. Guidelines are largely silent on these areas.

Health Insurance Benefits – "Health insurance benefits" are the services contractually required to be provided under defined circumstances, and associated terms of payment or coverage, pursuant to the terms of an insurance policy. The policy is summarized in a certificate of coverage and typically includes coverage information for both in-network and out-of-network providers, the schedule of benefits and coverage terms, exclusions, coordination of benefits, and other provisions. A schedule of benefits includes details on the range of service types that are typically covered. Examples include inpatient and outpatient care, emergent and urgent care, and preventive services.

Additional examples of insurance benefit terms related to an EBS product include access to disease management programs, medical homes, specific provider networks or panels, or other programs or services that seek to facilitate the application of scientific evidence to increase the clinical effectiveness and cost-effectiveness of care.

Health Plan – A "health plan" is an insurance company, health maintenance organization, or similar organization that is in the business or providing health insurance benefits and policies. The term "health plan" is sometimes also used synonymously with a "health insurance policy" or plan of coverage. For the purposes of this report, health plan refers to a health insurance organization rather than a policy.

Lifestyle Services – "Lifestyle services" includes services of limited medical necessity that are provided primarily to enhance a person's lifestyle or convenience. Examples include drugs that allow users to perform an activity "on demand" or without consequences, ameliorate an imprudent binge, or modify the normal effects of aging. Other examples include cosmetic surgical treatments such as hair transplants and most types of cosmetic surgery, subject to exceptions such as reconstruction following mastectomy, repair of cleft lip and palates, or plastic surgery following trauma.

Long-Term Services and Supports – "Long-term services and supports" includes procedures, tests and technologies directed primarily to maintain a given level of health, capacity, or function over a long-term period, often combining clinical and non-clinical elements. Examples include, but are not limited to, assisted living, adult foster care, targeted supports, waivered services, long-term nursing home care, personal care attendants, and respite care.

Medically Necessary Services – "Medically necessary services" include procedures, supplies, tests, and technologies that meet the following criteria:

- They are appropriate and necessary for the diagnosis, cure, or treatment of the medical condition;
- They meet the standards of good medical practice in the medical community;
- They are not primarily for the convenience of the plan member or provider; and
- They are the most appropriate level or supply of service that can safely be provided.

Supportive/Enabling Services – Services, procedures, tests and technologies that are not clinical but are indirectly related to care and are supportive of overall health and/or enabling access to clinical care. Examples include (but are not limited to) transportation, housing assistance, and income assistance.

Interpretation of Charge

The Work Group spent considerable time considering the scope of its charge. The charge has several explicit components:

- The term "essential" was understood to mean a "minimum" yet sufficiently comprehensive set of services to support the long-term health needs of Minnesotans.
- The references to evidence-based health care and clinical effectiveness were understood broadly to support a benefit design that seeks to maximize the use of services known, based on scientific evidence, to improve health outcomes, and minimize the use of services for which evidence shows no benefit.
- The references to cost-effectiveness were understood as a desire to encourage benefit designs that seek to achieve better value – meaning the optimal health outcome for a given level of spending. Cost-effectiveness also is related to issues of affordability, as is the concept of "essential" benefits considered as a minimum.

Work Group members also had extensive discussions about the lack of clarity in some aspects of the charge. Specifically, there is no reference in the statute about how the EBS is intended to be used within the broader context of health reform. As a result, the Work Group, with guidance from MDH, discussed at length the following implicit areas of the charge to ensure that its observations and recommendations applied as broadly as possible and made usage distinctions, when deemed necessary:

- The EBS could be applied within the context of a universal coverage initiative or an individual mandate to purchase health insurance, possibly as the minimally qualifying coverage set. Alternatively, the EBS standard could be used as a minimum standard for individuals purchasing private coverage to qualify for subsidies based on a definition of "affordability."
- The EBS could be used within the existing private insurance market to achieve better value through insurance products that demonstrate improved clinical- and cost-effectiveness through services supported by evidence.
- The observations and principles regarding the EBS should be relevant when considering the relationship between cost sharing in insurance benefit design and the use of high value services. For example, in the case of high deductible health plans the EBS could be used to define a set of services that should have low or no cost sharing because financial barriers to using these services could result in avoidable health complications that are more expensive to treat than to prevent.

KEY ELEMENTS OF "ESSENTIAL BENEFITS"

The Work Group determined that the definition of "essential benefits" as referenced in the legislation and charge should include the following elements:

- The scope of covered services, with options ranging from very broad coverage such as Medicaid to more narrow coverage such as provided through individual market products seen today, including some plans that exclude benefit categories for specific products (e.g., maternity services).
- The affordability of coverage, including the inherent tension between affordability and the scope of coverage. A rich coverage standard, while improving access to services financed through the insurance package, may also result in a significant increase in premiums, greater use of ineffective or low-value services, and increased potential for harm from exposure to unnecessary care.
- The scientific evidence dimension seeks to, where possible, encourage services for which there is evidence of both clinical- and cost-effectiveness, or discourage services where there is evidence against either clinical- or cost-effectiveness. The evidence dimension was considered in two different ways, the first being whether or not there was evidence of benefit of a service in any circumstance for a patient (clinical effectiveness), and the second being comparison of the costs of treatments for the same medical condition (cost-effectiveness).

PURPOSE OF INSURANCE

Before these elements could be considered, a common understanding of the purpose of the coverage package must first be determined. Both the party who is purchasing the insurance product and for what purpose it is designed must be identified. Each population being covered has potentially significantly different medical, personal, and financial considerations.

The MDH charge indicated that the Work Group should be primarily focused on the private insurance market. In this market, individuals and employers purchase insurance packages in a market regulated primarily by the state (if fully insured) or jointly at the state and federal levels (if self-insured).

Insurance is purchased by these groups for two basic reasons: (1) to protect the individual against financial loss, and (2) to improve health status. These purposes can be in conflict with each other if it is assumed that medical services can only be accessed through the insurance mechanism and resources are limited. Such a situation would require that a choice be made between covering high volume, low-cost services that are provided to many individuals and covering high-cost, catastrophic expenses incurred by a few individuals. In determining if a service was essential, the Work Group assumed that medical services will continue to be accessible in a variety of ways, including direct reimbursement by the patient. The Work Group also discussed a societal interest in promoting overall population health, and the potential for the insurance coverage package to be used to further this goal.

Given the population being covered, it was concluded that the primary goals of the EBS should be as follows, in order of priority:

- To protect individuals from catastrophic financial loss;

- To optimize health status and outcomes, including both individual and population health, through the use of clinically effective, cost-effective, evidence-based health care services. For this purpose, a service should be considered essential if it is currently excluded from coverage only due to the shortened time horizon related to the employer insurance market, and including it may increase premium costs in the short run but decrease costs over time; and
- To ensure access to appropriate care by minimizing cash flow challenges for patients (as well as providers).

The Work Group's understanding of the EBS charge includes consideration that affordability is a significant problem with health insurance today for many Minnesotans, some of whom may, as a result, require public subsidies, go without insurance, or forego certain necessary services due to cost sharing barriers. While developing a program of subsidies to address the problem of affordability was outside the scope of the Work Group charge, one important purpose of the EBS is to address the purpose of health insurance carefully. This includes ensuring that health plans are able to offer a set of benefits that reflects the purpose of insurance in a way that makes it possible for more Minnesotans to purchase health insurance without the need for government subsidies. In other words, the Work Group was concerned that an overly comprehensive EBS could result in higher premiums and make coverage less affordable overall.

The Work Group also discussed another benefit of health insurance in terms of a group purchasing function on behalf of members. Insurers are generally able to negotiate more favorable prices on behalf of members than the members may have been able to obtain on their own. Although there is a need to balance affordability and comprehensiveness in the EBS, for some types of services enrollees could still be allowed to access these negotiated discounts even if they are not included in the list of covered services or, therefore, in the premium. Before proceeding in this direction, the Work Group recommends that plans carefully consider if applying this approach would indeed lead to lower costs for members. It considered the possibility that for some types of services, due to complexities of provider contracting, this approach could actually lead to cost increases over what consumers would pay directly.

FEDERAL HEALTH REFORM

Finally, the Work Group acknowledges that its work coincides with a period of intense activity at the federal level concerning national health reform. While the final outcome of these efforts is unknown, if federal health reform legislation is adopted it is likely that it will have at least some effect on this report's recommendations. For example, if some form of individual coverage requirement is adopted and related benefits criteria are defined, those criteria are likely to address some of the same topics as this report and recommendations. The Work Group believes that its conclusions and recommendations have merit and should be considered in Minnesota within the framework of any possible federal health reforms, to the extent that states may be granted flexibility in how federal reforms are implemented.

Work Group Observations and Conclusions

EVIDENCE-BASED HEALTH CARE BASICS

The volume, scope and complexity of health care research are vast – and a reflection of the scope and complexity of health care itself. Research includes both: (1) clinical research, such as epidemiological studies and clinical studies about the impact of particular interventions on health care quality and cost, and (2) health services research, such as studies of various practices and initiatives by health care organizations and their impact on health care access, quality and affordability.

In recent years, health care research has increasingly been compiled in the form of "guidelines" that provide specific recommendations and guidance for the care across a specific spectrum of patient conditions or circumstances. Examples of conditions or services for which guidelines exist include diabetes care or adult preventive care. The EBS Work Group charge specifically referenced a local Minnesota organization that develops health care practice guidelines, the Institute for Clinical Systems Improvement (ICSI). ICSI currently maintains 59 guidelines ranging from preventive services to a variety of chronic conditions, most of which are geared toward providers but some of which are directed to patients and families. (See Appendix B for a list of current ICSI guidelines.) A typical guideline may be over 100 pages in length, and includes complex descriptions and clinical decision guidance incorporating numerous variables.

Many other groups are also involved in the development and dissemination of guidelines, including federal agencies such as the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ), and a broad range of professional and academic organizations. It should be noted, however, that the majority of health care research is not in the form of broad guidelines encompassing an entire range of services, but addresses more specific and discrete issues involving health care practices and patient outcomes. Guidelines build on such research, but research is not necessarily incorporated in or intended for guideline development.

Scientific research and evidence pertaining to clinical care and health services are relevant to deciding how to design an EBS. However, health care research is primarily oriented toward improving the quality of care related to specific conditions using specific interventions, and is generally written with a technical provider audience in mind. In terms of their applicability for health insurance benefit design, the results of scientific studies and guidelines range from relatively simple conclusions or standards that can be translated directly to insurance benefits (e.g., primary prevention), to much more complex conclusions or standards for which direct translation to benefit design is not yet directly feasible (e.g., chronic disease management). For example, chronic disease guidelines typically go far beyond simple lists of suggested services and are comprised of complex decision processes that assist providers in navigating the many considerations that factor into medical care for an individual patient.

Not all scientific evidence is equally rigorous or conclusive. For example, ICSI typically grades underlying evidence on a quality scale that ranges from randomized, controlled trials at the highest level, to medical opinion or consensus at a lower level. Specific medical conclusions within

the guidelines are further graded, ranging from Level I = Good Evidence, to Level III = Limited Evidence, and Level IV = Contrary to Evidence, Not Recommended (these are ICSI grading scales; other research organizations may apply different scales). Potential conflicts of interest should also be assessed and included in the evidentiary evaluation. Complex guidelines often contain multiple medical conclusions and each conclusion carries a grade. As a result, the quality of evidence on which a specific guideline is based usually cannot be classified as "all Level I" or "all Level II."

Finally, there are also many services for which there is no definitive guidance based on scientific evidence, or the available evidence is not sufficient to be conclusive. In these areas, the standard of care is more commonly based on health care professional consensus or "standards of practice," often established by specialty practice groups. Whether or not scientific studies are available, clinical judgment is also necessary to determine the most suitable course of treatment for an individual patient's unique circumstances. Clinicians may also engage patients in shared decision-making where appropriate and where there are multiple therapeutic approaches supported by evidence to varying degrees.

SCIENTIFIC EVIDENCE – STATUS AND OPPORTUNITIES

At present, new technologies and procedures tend to be judged primarily on safety and efficacy, but not necessarily on cost. Comparative Effectiveness Research (CER) that speaks to the clinical- and cost-effectiveness of two or more procedures compared to each other is beginning to emerge, but is still in its early stages for most service categories. Compared to other developed countries, CER in the U.S. is still quite limited and funded at much lower levels. While significant dollars are beginning to flow to new research as a result of the recent American Recovery and Reinvestment Act (ARRA), many areas of health care practice are likely to remain largely untouched as it relates to CER for the foreseeable future. Additionally, even when research exists, in many instances there remains a lack of clear evidence about what works and what does not. For example, some CER research does not directly compare protocols or treatments on a direct head-to-head basis. As this body of knowledge grows, it will become easier to identify which services are clinically effective and cost-effective.

Nonetheless, the application of scientific principles and standards of practice to the practice of medicine is growing. There are many organizations and a growing body of scientific work evaluating the effectiveness of various treatment regimes and measuring the quality of care received by patients in quantitative ways. ICSI, AHRQ, the National Committee for Quality Assurance (NCQA, sponsor of "HEDIS" measures), and Minnesota Community Measurement (MNCM) are all examples of organizations and processes dedicated to evaluating and /or improving the quality of care delivery:

- The Institute for Clinical Systems Improvement (ICSI) is an independent, non-profit organization that helps its members provide evidence-based health care services to people in Minnesota and surrounding states. ICSI comprises 57 medical groups representing 9,000 physicians, and is sponsored by six Minnesota and Wisconsin health plans. It works to demonstrate collaborative and innovative processes, uniting diverse stakeholders in the health care system to deliver patient-centered and value-driven care. Its mission is to champion the cause of health care quality and to accelerate improvement in the value of the health care delivered to the populations its members serve. ICSI's vision is to be a

collaboration that is deemed essential by its members for their improvement of health care and deemed essential by the community as a trusted voice for quality in health care. (See www.icsi.org.)

- The Agency for Healthcare Research and Quality (AHRQ) is the nation's lead federal agency for research on health care quality, costs, outcomes, and patient safety. AHRQ is the health services research arm of the U.S. Department of Health and Human Services (DHHS), complementing the biomedical research mission of its sister agency, the National Institutes of Health (NIH). AHRQ is home to research centers that specialize in and fund major areas of health care research, including: (1) quality improvement and patient safety, (2) outcomes and effectiveness of care, (3) clinical practice and technology assessment, (4) health care organization and delivery systems, (5) primary care (including preventive services), and (6) health care costs and sources of payment. AHRQ serves as a science partner, working with the public and private sectors to build the knowledge base for what works and does not work in health and health care and to translate this knowledge into everyday practice and policymaking. (See www.ahrq.gov.)
- The National Committee for Quality Assurance (NCQA) is a private, not-for-profit organization dedicated to improving health care quality. NCQA has helped to build consensus around important health care quality issues by working with large employers, policymakers, doctors, patients, and health plans to decide what is important, how to measure it, and how to promote improvement. Health plans in every state, the District of Columbia, and Puerto Rico are NCQA-accredited. These plans cover 109 million Americans, or 70.5 % of all Americans enrolled in health plans. The NCQA is also the sponsor for the widely publicized Healthcare Effectiveness Data and Information Set (HEDIS), as referenced on the following page. (See www.ncqa.org.)
- Minnesota Community Measurement (MNCM) is a collaboration of health care organizations and professionals dedicated to improving the quality of care through a collaborative effort in Minnesota on the premise that "you cannot improve what you don't measure." MNCM includes medical groups, clinics, physicians, hospitals, health plans, employers, consumer representatives, and quality improvement organizations. MNCM supports the notion that greater transparency will lead to better health outcomes for the people of Minnesota. Its mission is to accelerate the improvement of health by publicly reporting health care information (See www.mncm.org.) MNCM runs two web-based programs:
  - "Minnesota Health Scores" is a non-profit website that provides objective information on the quality of health care in Minnesota and surrounding areas. (See www.mnhealthscores.org.)
  - "D5 for Diabetes" is a set of five treatment goals that, when achieved together, represent the "gold standard" for managing diabetes. Reaching all five goals greatly reduces a patient's risk for the cardiovascular problems associated with diabetes. The D5 website is targeted to diabetes patients to encourage them to learn about the five goals and work with their health care team to achieve them. The website also reports MNCM's clinic results for this diabetes measure. (See www.thed5.org.)

These organizations have developed methodologies for evaluating the clinical effectiveness of various services within treatment regimens and generally accepted retrospective measures of the

quality of care received by patients. While most treatment regimens are too complex to be efficiently evaluated for medical necessity and appropriateness in order to determine health insurance coverage at the time of service, the work of these groups could be used to retrospectively evaluate the care that was provided. Programs, providers, and/or networks could then be graded for quality based upon agreed-upon standards, and product designs could be developed around them.

One recent example of this type is from the state of Pennsylvania. The Pennsylvania Health Care Quality Alliance publishes detailed quality measures of hospitals operating in the state. Insurers and self-insured employers develop insurance products that have lower enrollee cost sharing for hospitals that have better scores on quality measures, or that exclude services provided by facilities with lower scores. Improved outcomes have been reported. (See http://www.phcqa.org/.) The State of Minnesota's employee group insurance program is another example of an insurance benefit design that uses enrollee cost sharing to encourage use of more efficient providers, although the benefit tiers do not explicitly include quality measures.

The potential opportunity associated with such products has been demonstrated by numerous studies that highlight wide variation in the delivery of health care services that is not supported by differences in patient characteristics or needs. The following are examples of recent studies, reports, and articles concerning such practice variations:

- The Dartmouth Atlas of Health Care is the landmark and widely cited source of practice variation studies. For more than 20 years the Dartmouth Atlas Project has documented glaring variations in how medical resources are distributed and used in the United States. The project uses Medicare data to provide comprehensive information and analysis about national, regional, and local markets, as well as individual hospitals and their affiliated physicians (www.dartmouthatlas.org).
  - A recent study found that just 30% of the excess spending in the highest-cost regions could be attributable to income and health, leaving the vast majority of expenditures due to regional factors. The findings reinforce the longstanding Dartmouth Atlas conclusions that variations in spending across regions and hospitals provide evidence of important opportunities to reduce the costs of U.S. health care.[1]
  - Studies of the treatment received by a million elderly Americans diagnosed with colon or rectal cancer, a hip fracture, or a heart attack found that patients in higher-spending regions received 60% more care than elsewhere. They got more frequent tests and procedures, more visits with specialists, and more frequent admission to hospitals. Yet they did no better than other patients, whether this was measured in terms of survival, their ability to function, or satisfaction with the care they received. If anything, they seemed to do worse. [Source: see *New Yorker* article referenced below.]
- HEDIS – The Healthcare Effectiveness Data and Information Set (HEDIS) is a tool used by more than 90% of U.S. health plans to measure performance on important dimensions of care and service. It is the most widely used standard for measuring variations in health

[1] Sutherland JM, Fischer ES, Skinner JS. Getting past denial—the high cost of health care in the United States. (2009) *NEJM* 361(13):1227 – 30.

plan quality performance. Highlights from 2008 data, reported by NCQA in October 2009, include:

- Improving health care quality would have significant benefits beyond the health care system itself. NCQA estimates that were all health plans able to perform at the level of the top 10% of plans, the U.S. would avoid up to 115,000 deaths and save at least $12 billion in medical costs and lost productivity every year.
- There were a few notable improvements in areas such as keeping heart attack patients on life-saving beta blocker drugs and delivering flu shots.
- There were disquieting declines in several measures related to mental health, diabetes care, the overuse of imaging for low back pain, and breast cancer screening. (See http://www.ncqa.org/tabid/1077/Default.aspx.)
- For more on HEDIS see: http://www.ncqa.org/tabid/59/Default.aspx

- New Yorker article – The article "The cost conundrum: What a Texas town can teach us about health care" by Atul Gawande, MD was published in *The New Yorker* magazine on June 1, 2009. The article highlighted dramatic differences in total Medicare expenditures between the communities of McAllen and El Paso, Texas, despite similar population demographics and morbidity. The article has been widely cited in recent federal health reform discussions. Noteworthy disparities included in the article:
  - Between 2001 and 2005, critically ill Medicare patients received almost 50% more specialist visits in McAllen than in El Paso, and were two-thirds more likely to see ten or more specialists in a six-month period.
  - In 2005 and 2006, patients in McAllen received 20% more abdominal ultrasounds, 30% more bone-density studies, 60% more stress tests with echocardiography, 200% more nerve-conduction studies to diagnose carpal-tunnel syndrome, and 550% more urine-flow studies to diagnose prostate troubles.
  - In 2005 and 2006, patients in McAllen received one-fifth to two-thirds more gallbladder operations, knee replacements, breast biopsies, and bladder scopes. They also received two to three times as many pacemakers, implantable defibrillators, cardiac-bypass operations, carotid endarterectomies, and coronary-artery stents.
  - In 2005 and 2006, patients in McAllen received five times as many home-nurse visits paid for by Medicare paid.
  - http://www.newyorker.com/reporting/2009/06/01/090601fa_fact_gawande
- MNCM – This Minnesota initiative gathers data from health plans across the state and is developing performance measures at the clinic level. One of the more striking examples of variation and adherence to standards include MNCM's data on diabetes care. MNCM's D5 standard assesses what percentage of a clinic's patients who meet all five of these goals:
  1) Maintain blood pressure less than 130/80
  2) Lower LDL or "bad" cholesterol to less than 100 mg/dl
  3) Control blood sugar so that A1c level is less than 7%

4) Don't smoke

5) Take an aspirin daily, for those ages 40 and older

MNCM reports that the highest percentage of patients meeting the goal at any single clinic is 45%, while the lowest is 0%. MNCM also reports similar outcome ranges for vascular disease and depression care. For vascular disease, the percentage of patients receiving the recommended best care ranges from 61% to 3% for different clinics, and for depression care the range is from 11% to 0%.

Many studies have also addressed the potential for improvements in quality and costs if health care delivery conformed more closely to scientific evidence regarding clinically effective and cost-effective treatments. The following are several examples:

- A study of chronic disease prevention and diabetes care found that investment in an intensive disease control protocol (vs. the conventional protocol) would lead to average annual savings of over $400 after 10 years and almost $1,200 after 10 years.[2]
- A randomized controlled trial published in the American Journal of Managed Care in 2005 found that a clinical decision system decreased medical expenses by approximately $223 Per Member Per Year. Such systems are defined broadly as information systems that link health information with health knowledge to improve clinical decision making and enhance patient care.
- A recent study by Thomson Reuters compiled various research sources to estimate potential health system savings from improvements across multiple categories. The largest category in terms of potential savings was "unwarranted use," defined as care that provide no or only marginal value to either the diagnosis of a patient's condition or effective treatment of a diagnosed condition. This category was estimated to hold potential for savings in the range of 13% from current expenditure levels. Other categories with significant costs savings potential include reduction of health care provider errors (4%), reduction of preventable conditions (2%), and improved care coordination (2%).[3]

PRACTICAL CONSIDERATIONS

Access to scientific research, evidence and guidelines concerning health care services are a necessary but insufficient prerequisite to developing an EBS grounded in those principles. There are a variety of practical considerations that must be considered in applying scientific evidence regarding health care services to insurance benefit design. These include issues related to the administration of an insurance product, the types of data and systems necessary to distinguish "evidence-based" services from other services, and the need to communicate the rules of what is

[2] Michael J. O'Grady, PhD, University of Chicago. Using Clinical Information To Project Federal Health Care Spending – How Congress Could Use A Diabetes Spending Projection Model to Help Inform Budget Decisions. Health Affairs, doi: 10.1377/hlthaff.28.5.w978 (Published online September 1, 2009) © 2009 by Project HOPE

[3] Robert Kelley, Vice President, Healthcare Analytics, Thomson Reuters, "White Paper: Where Can $700 Billion in Waste Be Cut Annually From the U.S. Healthcare System," October 2009, 30 pages, available at http://thomsonreuters.com/content/corporate/articles/healthcare_reform

covered and at what level to patients and providers in an understandable and timely manner. The following is a partial list of such practical considerations:

Insurance Administration Issues

- *Claims administration* – Claims systems must be sufficiently robust to support the research-based product design. Depending on the EBS design, it is possible that additional member or claims data elements not traditionally stored within claims adjudication systems may be required to adjudicate EBS cost sharing properly.
- *Data privacy* – To the extent that new types of data may be necessary from patient medical records to implement a research-based insurance design, or to personalize cost sharing incentives as a means of improving their effectiveness, additional privacy and confidentiality issues will need to be considered.
- *Health care IT* – While health information technology is advancing, many health care providers do not have advanced health care information systems and many systems remain unable to communicate with one another. Significant advances are still needed before most plans or providers will be able to identify specific patients who are out-of-compliance with a particular guideline on a "real time" rather than retrospective basis.
- *Regulatory/legal challenges* – Health insurance is a highly regulated industry. Although a complete legal or compliance review is outside of the scope of the Work Group, an EBS incorporating on a new, evidence-based design is almost certain to require new legislation to ensure that it is aligned with other regulatory requirements.

Patient and Provider Communication

- *Status of EBS coverage* – Patients and providers must be able to understand which services will be covered by the benefit set, or at what level of cost sharing, before the services are provided. There is a tradeoff between the ability to design an EBS that provides lower levels of enrollee cost sharing for select services based on criteria of clinical- and cost-effectiveness, and the ability for consumers to easily understand the terms and structure of their health insurance coverage.
- *Compliance monitoring* – If monitoring of member compliance with a standard or guideline is required for the benefit design, information about member status and the consequences for covered conditions and services must be available in a timely, convenient, and accessible format so that it can be readily understood and accepted.
- *Reporting fraud* – A mechanism may be required in the EBS design to identify members who, by the nature of their conditions or use of services, qualify for lower cost sharing. Some members who may wish to qualify will not meet the standards. As a result, some providers or patients could misreport this information in order to become qualified. Providers may benefit from false improvements in future outcomes or from a feeling that they have helped out their patients monetarily.

Potential Unintended or Problematic Consequences

- *Short-term cost increases* – If an EBS benefit design lowers cost sharing for certain high-value services, the short-term consequence may be an overall increase in costs. To the

extent that the same services that previously were covered at a lower level are now covered at a higher level, more of the total cost will be paid for through premiums and less by the consumer out-of-pocket. In addition, lower cost sharing could affect total costs through higher utilization of services. Some of the additional costs may be partially offset by savings associated with more clinically- and cost-effective care. However, not all clinically effective services yield savings, and even cost-effective services may yield savings over the long-term rather than the short-term.

- *Adverse Selection* – If a new benefit set that lowers cost sharing for chronic conditions is offered next to alternative, more traditional plan designs, the new plan may attract a disproportionate share of members with chronic conditions. If premium rates are not able to adequately reflect this adverse selection, it may be appropriate to consider the inclusion of some type of market-wide risk sharing mechanism to mitigate the impact.
- *Employee/member turnover* – Member turnover can present a challenge for EBS design if members do not remain in a program long enough for the interventions to prove either clinically or financially effective. Greater workforce mobility creates pressure for a faster return-on-investment on these types of innovations. The more a program is able to target members who are out of compliance with evidence-based medicine and whose resulting condition is high-risk, yet correctable, the greater and faster the benefits, minimizing turnover concerns. Also, requiring these services to be covered by all insurance programs would eliminate or reduce the "free-rider" problem, where the plan that implements the preventive program incurs the cost, and a plan into which the member enrolls in the future receives the benefit.

EARLY CASE STUDIES

Interesting health plan experience on value-based insurance design (VBID) trials comes from self-funded employers. Some of these programs have recently begun to experiment with designs that create incentives for the use of high-value services, primarily by lowering cost sharing for maintenance drugs used to control chronic disease. While most of these programs are still in the early stages with results pending, some promising indications are being published. Many of these studies have stressed that they do not necessarily lead to cost savings in the short term, but rather seek to maximize the long-term value of future expenditures.

To date, most of these studies have been narrowly focused on drug therapy, with many financed by parties that have an economic interest in the outcome of the study. To obtain more mature results that are more broadly generalizable, additional research is needed.

These issues are discussed in greater depth in the VBID research literature. These studies include discussion of short-term cost increases vs. potential long-term savings. They stress that the primary benefit of VBID is not necessarily cost savings, but the ability to increase consumers' marginal value gained from a dollar of health spending. In terms of medical outcomes, VBID attempts to leverage a given amount of spending but produce better outcomes by incentivizing high-value services or providers. VBID is in some ways an extension of the consumer-directed health plan (CDHP) concept that aims to present consumers with actionable information regarding effective and efficient services and providers, and educating them about services that may otherwise have been under-utilized in a more traditional CDHP design.

The following are several case studies of organizations that have implemented programs incorporating VBID or related concepts to promote more clinically- and cost-effective health care services.

(1) United Healthcare – Diabetes Health Plan

In early 2009, United Healthcare rolled out a Diabetes Health Plan targeting diabetics and pre-diabetics who are interested in better managing their conditions, and employers looking to control costs for this portion of their populations. Members who follow medically proven steps to manage their conditions are given free testing supplies and drugs and lower copayments for doctor visits. Program participants have access to online monitoring and education tools. Participants must comply with evidence-based diabetes preventive care guidelines to remain in the plan.

(2) Diabetes Ten City Challenge (DTCC)

DTCC is also a diabetes-oriented program and is sponsored by the APhA Foundation with support from the pharmaceutical company GlaxoSmithKline. Employers taking part in the program provide members with diabetes a voluntary health benefit that waives copayments for diabetes drugs and testing supplies if they continue with the program. The program helps people manage their diabetes with the help of pharmacist coaches and reimburses community pharmacists for clinical services. The program currently includes 30 employers and hundreds of local pharmacists in ten cities. The DTCC model of "collaborative care" is available to employers nationwide through the HealthMapRx website (http://www.healthmaprx.com).

A report published in the May/June 2009 issue of the Journal of the American Pharmacists Association documents favorable economic and clinical results for employers and participants. Employers realized an average annual savings of almost $1,100 in total health care costs per patient when compared to projected costs if the DTCC had not been implemented, and participants saved an average of almost $600 per year. Participants also improved in all of the recognized standards for diabetes care, including decreases in A1C, LDL cholesterol, and blood pressure, and increases in current flu vaccinations and foot and eye exams.

(3) Hannaford Brothers Company

Beginning in 2004, this supermarket chain in the northeastern U.S. offered a new program that offered richer benefits for individuals who use top-tier providers. It supported this value-based purchasing approach by maintaining data on outcomes for patients and providers. It also included other incentives such as reduced cost sharing using a Condition/Severity approach and provided healthy behavior premium credits. Beginning in January of 2008, Hannaford Brothers added incentives to use non-invasive surgery at a particular medical center in Bangor, Maine, near its headquarters. Results from the Director of Associate Health and Wellness, Peter Hayes, include lower absenteeism, improved productivity, improved diabetes health as measured by lab results, reduced risk of heart attack, and lower cost through choosing top-tier providers (no specific dollar estimate was provided).

(4) State of Oregon Essential Benefit Package (EBP)

The state of Oregon has developed a version of an EBS based on the Oregon Health Services Commission's Prioritized List of Health Services. This list, which has been in partial use for the state's Medicaid population since 1994, uses an evidence-based approach for determining coverage priorities. The structure of the list is based on "condition/treatment pairs" which are then ranked according to evidence of effectiveness and modified biannually by the citizen commission with technical support. For example:

- Maternity care is the highest priority and is available with little or no cost sharing. Preventive care is also high priority and, in the Oregon EBS, little or no cost sharing is required for these high value services.
- High priority is also assigned to "value-based services" targeted at maintaining individuals with chronic illnesses, basic diagnostic services, and comfort care services including hospice and palliative care.
- Lower priority is assigned to services provided in specialist offices, emergency rooms, and hospitals as incentives for the use of primary care when appropriate. In the Oregon EBS, additional cost sharing is then applied to these lower priority items.

The Oregon list also integrates both mental and dental health with physical health and contains practice guidelines and prevention tables to promote evidence-based medicine. The inclusion of diagnosis allows for variability in benefits by condition so services that benefit a particular condition can be supported for that particular condition. This approach uses existing service and diagnosis codes, can be handled as part of concurrent claims review, and can be communicated to patients by equating a given condition to a list of encouraged services.

Creating a prioritized list of health services is, however, very complex to develop and time intensive to maintain, which was one reason why it was not pursued by the Work Group. Additionally, challenges arise for including some type of services and procedures within the prioritized list. Also, while procedure and diagnosis are key data elements for evaluation, many other variables are commonly taken into account in health care research and related practice recommendations or guidelines. For this reason, a ranking system based primarily on procedure and diagnosis data can only provide a limited approximation of most evidence-based standards.

MARKET FAILURES AND CHALLENGES

Fundamental questions related to the Work Group charge include the extent to which health plans are already implementing evidence-based insurance products, and what barriers may exist that limit the more widespread or rapid development of such products. To address these questions the Work Group reviewed information concerning current health plan products, and the extent to which market structure or regulatory barriers exist that may limit development of insurance products that effectively promote services that research has shown to be more clinically- and cost-effective. While an in-depth assessment of insurance regulation was outside the scope of the charge, the Work Group's limited review included the following issues:

- Time horizon for "investments"
- Potential for biased selection
- Health plan activities to apply evidence
- Practical and legal barriers to implementation
- Consumer barriers to obtaining recommended care
- The challenge of new and costly health care services

Each of these issues is addressed in detail below.

Time Horizon for "Investments"

The Work Group reviewed structure and economic "rules" of the current health insurance market that may present barriers to benefit designs that fully take advantage of available evidence about clinically- and cost-effective care. One such area is the time horizon on which health plans make coverage decisions. For example, some employers make consider coverage decisions in the context of shorter-term risk management and employee turnover. While Minnesota health plans do not report that the time horizon issue is a major factor for their benefits planning, for some employer clients it may lead to a prioritization of benefits and related programs or "investments" that stress shorter-term savings. By contrast, it may be possible to improve health outcomes and further reduce costs by taking a longer-term view in cases where the improvement in health status is achieved over many years rather than within a relative short time after the service is provided.

The benefit design for mental health coverage is a potential example. Some studies have shown that, when untreated or poorly treated, mental illness is associated with doubling or more of total health care costs, mainly from increased use of physical health services.[4] Studies have also shown that providing outcome-changing mental health care to patients with depression in a primary care setting may result in sustained lower total health care cost for up to four years after the introduction of depression treatment.[5] A longer-term "investment" horizon may lead to higher priorities for benefits and programs with these types of programs where the returns are realized over a longer period and require more continuous enrollment than is common in the current marketplace.

Additionally, society may take a broader population health perspective than a given employer or individual in prioritizing health insurance benefits. A societal perspective may lead to consideration of secondary impacts from coverage decisions if those impacts proved to be closely related to health benefit decisions. For example, effective treatment of serious mental health or chemical dependency conditions may reduce long-term societal costs associated with incarceration. Most health coverage in Minnesota is provided through health plans that are non-profit and locally based, which creates a structural incentive for a longer-term health care investment perspective that is more comparable to a societal perspective. Minnesota health plans' sponsorship of and

[4] R. Kathol, Saravay, Lobo, & Ormel, 2006; R. G. Kathol et al., 2005; Simon & Unutzer, 1999; Thomas, Waxmonsky, McGinnis, & Barry, 2006; Trudeau, Deitz, & Cook, 2002.
[5] Gilbody, Bower, Fletcher, Richards, & Sutton, 2006; Gilbody, Bower, & Whitty, 2006; Katon & Seelig, 2008; Seelig & Katon, 2008.

participation in organizations such as ICSI and MNCM are examples of a longer-term investment perspective.

Potential for Biased Selection

In their benefit design and product offering decisions, health plans must consider "selection bias" issues that directly impact their financial performance. Such considerations may lead to decisions to avoid offering certain services or benefits that run counter to what society as a whole may otherwise choose. For example, a plan that became known as the "leader" for serving certain chronic illnesses, such as hypertension or mental health conditions, may attract a disproportionate number of members with those illnesses. If other plans did not follow suit with similar programs, the "leader" plan may elect to discontinue them rather than experience adverse selection (and its associated higher per-member cost). While it is difficult to prove such effects by the absence of programs that health plans might otherwise have pursued, Work Group members discussed health plans' awareness of competitor initiatives and potential selection impacts. It was noted that if a particular initiative created adverse selection risks and was not adopted uniformly across the marketplace as a "value added" program demanded by purchasers, it may be scaled back or discontinued.

The Work Group noted that there is greater potential for biased selection issues to arise in the individual market than the group market. In the group market, health coverage decisions are made by the employer on behalf of a group of employees as part of a total benefits and compensation package. While an individual purchaser may consider disease management programs specific to their needs, employers are more likely to emphasize more general features of a health insurance product and its suitability to their group coverage needs. In addition, the potential for biased selection in the individual market is mitigated to some extent by standard health plan underwriting procedures that limit opportunities for individuals to "shop" for coverage only when services may be needed.

Health Plan Activities to Apply Evidence

Health plans currently apply a variety of techniques to promote the use of clinically- and cost-effective services and to limit coverage for services that are not considered "medically necessary." See the Appendix C discussion document "MCO Tools and Initiatives to Manage Costs Based on Service Value, Quality or Necessity" for a more complete list of these activities. Health plans make exceptions in some cases to expand standard coverage where the additional benefit is clinically indicated for a specific patient and is cost-effective. In Minnesota, health plans are also supporting or applying scientific evidence to health care coverage through various programs and initiatives, including but not limited to participation in ICSI, adoption of disease management and care management programs, promotion of therapeutically-equivalent generic drugs, and programs directed to consumer behavior such as health promotion and risk assessments.

Much progress has been made in Minnesota through these various activities and programs to contribute to the use of more clinically- and cost-effective care. However, considerable opportunities for improvement still remain. As noted earlier, across a wide variety of conditions and practice measures there remain large gaps between the potential for improved adherence to

recommended standards and guidelines and actual experience, as well as the elimination of care proven not to be clinically- or cost-effective.

In terms of potential improvements in outcomes and efficiency, this gap is especially significant for the small but very expensive group of individuals with multiple chronic and interactive illnesses for which consistent and coordinated high intensity health support is difficult to achieve. New benefit design concepts have been proposed or tested to improve care coordination and the application of evidence, including but not limited to "Medical Homes" and "Accountable Care Organizations." These concepts emphasize reimbursement structures that support care coordination for complex patients at the clinic level rather than "top down" from the health plan. These designs are not yet in widespread use in Minnesota, but should be carefully assessed to determine their potential to promote greater use of clinically- and cost-effective care.

Practical and Legal Barriers to Implementation

In Work Group discussions, health plans did not report significant "barriers" in the form of specific regulations or market structure limitations that directly prevent designing benefit packages to target the coverage of services that are clinically effective. However, there nevertheless appear to be several practical barriers to this form of benefit design.

Health plans reported limited awareness or sophistication among health insurance purchasers of the issues or opportunities associated with this form of benefit design, such as the potential for increased value or lower costs. In this regard, it is instructive to note that much of the innovation in this area has taken place in the larger, self-insured market, where there is much more regulatory flexibility around the benefit design, and the purchaser (the large employer) has a financial incentive due to the population size and stability more consistent with overall population health incentives.

Treatment decisions are primarily made between the patient and the provider, and as discussed above, related guidelines (where applicable) are generally too complicated to incorporate directly into a coverage design. Nearly all services currently covered in standard benefit designs are appropriate in some circumstances. Health plans currently attempt to apply evidence and guidelines through a variety of mechanisms, as discussed elsewhere in this section (see also Appendix C, MCO Tools and Initiatives to Manage Costs Based on Service Value, Quality or Necessity). However, many of these mechanisms tend to be inefficient, delay treatment, or put the patient at financial risk.

Health plans also reported in Work Group discussions that there may be resistance to scientific evidence-based initiatives from health care providers and consumers. Many private and public studies have been performed investigating barriers to implementing best practices and improving quality measures. These studies commonly find that the largest barrier to improving outcomes and quality is changing the beliefs and practices of patients and their care providers. The direct marketing to consumers of services and technologies that are not based on scientific evidence can also add to these barriers to the degree they may encourage patients to use services that are unnecessary or not cost effective.

Finally, the Work Group considers that one likely barrier to health insurance products that rigorously promote evidence-based health care is potential legal liability. While this cannot be

demonstrated with certainty until such products are developed and implemented, there are many cases of health plans being the target of litigation based on their perceived "intrusion" in the practice of medicine. A key premise of a benefit design to promote clinically- and cost-effective care is that some services will be determined to meet this standard and other services will not. While health plans have long applied medical necessity standards and other methods to limit coverage for services of limited value, an evidence-based benefit design would entail a more systematic and comprehensive approach to service inclusion and exclusion. To the extent that such an approach may create a new arena for litigation challenging the premise of such benefit designs, a "chilling effect" may be realized that would inhibit the development of such products.

Consumer Barriers to Obtaining Recommended Care

For persons with insurance, based on the experience of Minnesota health plans as reported to the Work Group, factors other than cost-sharing differentials appear to have a greater impact on access to and utilization of preventive care or other services that are recommended as clinically- or cost-effective. For example, utilization remains fairly low for many recommended preventive services that are already often covered at 100%. Furthermore, research studies comparing similar, privately insured populations appear to indicate that there is little if any difference in HEDIS measures between products that have relatively low cost sharing and those with high deductibles.[6] Further research may be warranted to the extent that recent studies of the impact of cost sharing on access to care may not have adjusted sufficiently for socioeconomic differences.

Other factors that appear to have a greater influence on obtaining recommended care include, but are not limited to: outreach and reminders to obtain recommended care; the value assigned by consumers to recommended care; busy schedules or other personal barriers; and other barriers to care such as transportation, language (interpreter availability) or culture. Encouraging benefit designs that support coordination and outreach activities, such as through medical homes, and patient education and reminders, may be more effective at improving adherence to prevention and chronic disease management guidelines.

The Challenge of New and Costly Healthcare Services

The introduction of new health care services, or the extension of existing services for new and unproven purposes, drives a significant amount of cost increases each year. The U.S. Food and Drug Administration (FDA) is limited to assessing the efficacy and safety of new drugs, devices, and biotechnologies. It does not review their costs or compare the efficacy of alternatives. Moreover, there is no approval process available to formally evaluate new health care procedures comparable to the federal review processes for new drugs and medical equipment. As a result, new procedures and technologies can become established and associated costs incurred even if they are eventually shown not to be cost-effective or offer worse clinical outcomes than other services. By that time, the procedures and technologies are likely to have developed an economic and political constituency such that they cannot easily be excluded from coverage by the insurer. A more formalized and consistent process to address this issue in Minnesota could limit the incidence of

[6] CIGNA Choice Fund Experience Study. January, 2009. Robinson, J. Consumer-Directed Health Insurance: The Next Generation. Health Affairs. Dec 13, 2005.

new procedures and technologies coming into widespread use before their clinical- or cost-effectiveness has been demonstrated, and the associated potential for increased risk of harm to patients.

KEY CONCLUSIONS

The following is a summary of key Work Group conclusions related to the current market for privately purchased health insurance, and forms the basis for the Work Group's recommendations:

- Government definition of an EBS carries the premise that the market has somehow produced the wrong answer. Specifying an EBS should be accompanied by a clear explanation of exactly what went wrong in the market, why it went wrong, and why specifying benefits is the best solution to whatever the problem is thought to be.
- The coverage of health care services in the private market is generally (although not always) sufficient to encompass services that are necessary, clinically effective, and cost-effective. However, benefits are generally structured so broadly that they include services that are both effective and ineffective. That is, if a service can be effective in any situation, it may be covered in all situations (including when not effective).
- The current state of health care services delivery presents significant opportunity to improve outcomes and reduce costs both through increased use of effective services and, of equal importance, decreased use of ineffective services. While changes in benefit design may play a role, other strategies such as provider network design and payment reforms are also needed to more fully realize this opportunities for improved system performance.
- The determination of whether services have been provided in a clinically- and cost-effective manner is, in most but not all cases, too complex to evaluate and administer through standard covered service descriptions as expressed in health insurance product language, or through standard claims adjudication processes.
- Member cost sharing, while potentially presenting a barrier for some in accessing effective care, also serves as a deterrent to accessing inappropriate and potentially harmful care by incenting members and providers to consider the appropriateness, clinical effectiveness, and cost-effectiveness of services. In the private market, initiatives directed at changing patient and provider behavior are generally more important factors in improving health outcomes than cost sharing.
- In some cases, the short time horizon in the employer market can serve as a deterrent to investing in preventive health, care coordination, disease management, and other activities that increase costs in the short run but may improve long-term health outcomes.

Work Group Recommendations

KEY ASSUMPTIONS AS BASIS FOR RECOMMENDATIONS

The Work Group identified the following assumptions as: (a) background for its overall recommendations, (b) specific to the charge of EBS development, and (c) specific to current market applicability.

Assumptions as General Background for Overall Recommendations

- Neither individual nor population health is solely a function of coverage for essential health services. However, coverage for essential services is a necessary component of individual and population health.
- Some policymakers are concerned that high deductible insurance plans may be preventing people from getting needed services in a timely way, thus undermining individual and population health.
- There should be no or limited financial barriers to obtaining high-value services, recognizing that what constitutes a financial barrier may be different for different people.
- The Work Group's task is essentially normative: What should be in the EBS and what cost-sharing elements should be used to promote people getting appropriate health care services in timely, cost-effective ways?
- The Work Group should address two overarching value judgments:
  - What should the (or "an") EBS include to promote individual and Minnesota population health in the long term?
  - What approaches to cost sharing should be used to incent consumers to choose high-value services among covered services?
- Decisions about EBS inclusions, exclusions, and cost sharing tiers should be evidence-based, where possible. Evidence about clinical- and cost-effectiveness should be the basis of decisions to include, exclude, or adjust cost sharing for services in the EBS, where possible.
- In addition to evidence, degrees of clinical consensus may be considered when evidence is lacking regarding EBS or VBID decisions.
- The Work Group should select criteria and procedures to make decisions about EBS inclusions and exclusions.
- Implementation concerns in relation to the Work Group's EBS and VBID recommendations should not constrain the Work Group's development of the EBS or the VBID options. The Work Group's task is to make value judgments about what health services are important to meet individual and population health goals, not to determine whether and how to operationalize them. The Work Group should strive to set a minimum essential standard but not address subsidies or implementation beyond

considering cost sharing as part of the Work Group's charge. Policymakers will need to address tradeoffs involving affordability and subsidies separately.

- Statutory or regulatory change may to be necessary to effect the Work Group's recommended EBS and VBID options.

Assumptions Specific to the Charge of EBS Development

- The EBS should include services minimally essential to promote the life-long health needs of all Minnesotans.
- The EBS should cover services necessary to support individual health and population health.
- Currently mandated and commonly covered benefits should be reviewed by the Work Group for possible inclusion or exclusion from the EBS.
- The EBS should protect insureds from the catastrophic costs of serious medical problems.
- Customers, employers, other group purchasers, and individuals could have the option of covering more than the EBS.

Assumptions Specific to Current Market Applicability

As discussed in the section on interpreting the Work Group charge, it is recognized that the potential uses of the EBS relate both to a mandated / universal coverage scenario and to the private insurance market "as it is." The Work Group recommendations are intended to address both situations, and those related to the universal coverage scenario build on and incorporate the current market recommendations unless stated otherwise.

Recommendations #1-11 are applicable to the current market for private health insurance, and are based on the assumption that the market will continue to have the following characteristics:

- The "Essential Benefit Set" product represents a new type of health insurance product. The EBS product is not the minimum standard of services that must be covered by any health insurance product in the market.
- A variety of health insurance products will continue to be available for sale. Products can offer benefits in excess of the EBS design.
- Programs such as Medicaid and MinnesotaCare will continue to be available, but no premium subsidies will be available in the private health insurance market.
- There is no individual mandate to obtain health insurance.
- Current regulations regarding premium rate setting, including limits on premium differentials related to age banding and other demographic factors, will continue to be in place.
- Except as recommended below (see recommendation #11), there will not be any cross-plan subsidization or changes to current rate-setting regulation (e.g., community rating) or regulations related to underwriting or related premium adjustments.

Modifications to these assumptions may substantially affect the recommendations. Recommendations #1-11 are also applicable to a mandated coverage scenario as part of a universal coverage program, as are two additional recommendations that are subject to a different set of assumptions (see recommendations #12-13). Finally, recommendation #14 addresses problems best handled outside the EBS framework.

EBS CERTIFIED PRODUCT

1. EBS Definition

For the reasons described in more detail below, the Work Group decided not to develop a specific list of covered services and cost sharing recommendations for those services as its recommended Essential Benefit Set. Instead, the Work Group recommends that an "Essential Benefit Set Certified Product" be defined as any health insurance product that provides coverage based on scientific study and evidence of clinical- and cost-effectiveness, as described in recommendations #2-6 below, and not in terms of a static list of services.

The Work Group decided against defining the EBS in terms of a static list because of the complexity of health care research and related evidence, standards, and guidelines, combined with the continually changing "state of the art" concerning best practices. Any static or simple list will be unable to capture the rich complexity of scientific research and recommendations related to a particular condition, population, or set of circumstances. This does not mean that evidence of clinical- and cost-effectiveness cannot be applied to health insurance benefit design, but that the means for doing so must be different than the standard lists and descriptions of covered services currently used in health insurance certificates of coverage.

Physician office visits provide an example of the difficulty of applying a static list to capture the key elements of evidence-based recommendations for benefit design. Every health insurance plan covers physician office visits to some degree, and virtually every best practices standard or guideline is likely to include some physician office visits. However, there are unlimited possible variations of circumstances in which a specific patient may have an office visit. Whether or not a particular office visit is a case of the very best, evidence-based practice, or completely wasteful and counter-productive, will depend on a range of variables including but not limited to:

- Procedure – the particular type or level of office visit
- Diagnosis – the patient's health condition(s) at the time of the visit (if any)
- Frequency – the interval since the last office visit
- History – the patient's health history and related family history
- Treatment regimens – the patient's eligibility for and participation in any disease management or other specific care regimens
- Other procedures – recently completed or future planned tests, therapies, surgeries, or other procedures that may be related to the purpose of the office visit
- Test results – the specific results of laboratory tests or radiology procedures that may be related to the purpose of the office visit

- Compliance – any patient-specific issues associated with the ease or difficulty of scheduling and fulfilling an office visit appointment
- Evidence – based on all of the above and any other relevant variables, the recommended timing, level, and need for this particular office visit

2. Basic / Comprehensive Coverage

The Work Group recommends that EBS Certified Products should provide a level of coverage that incorporates and balances the following criteria. Subject to these general criteria and the other specific criteria described below (recommendations #3-10), health plans should be afforded substantial flexibility to develop EBS Certified Products in a variety of ways. Qualification as an EBS Certified Product should not require coverage of a specific list of services or a specific member cost-sharing structure.

a. *Comprehensive* – The EBS should be comprehensive in terms of health conditions and services. It should encompass a broad range of clinical services, and should not arbitrarily exclude service categories based on health conditions or status.

   - To the extent feasible in the private market, consideration should also be given to extending coverage to include additional services based on a longer-term "return on investment" (ROI) period consistent with population health goals. This may include limited additions to (and not reductions from) the scope of coverage for services that are demonstrated to make a significant contribution to population health and are well supported by cost-efficiency evidence, and not supported exclusively by secondary considerations such as productivity gains. Consideration should also be given to whether funding for such additional services should be provided through public health or other programs separate from the EBS.

b. *Affordable* – The EBS should be affordable. To ensure that the EBS is not less affordable than currently available coverage, an "affordability benchmark" should be established based on consideration of average total health care expenses, including premium levels and out-of-pocket costs, paid by consumers in the private insurance market relative to household income. Prospective biased selection adjustment payments (see recommendation #9) should be taken into account in assessing affordability.

   - Persons with existing health conditions will tend to have above average health care expenses, and will therefore be more likely to reach insurance out-of-pocket limits.
   - Subject to overall affordability criteria, some level of member cost sharing is considered beneficial for the purposes of: (1) incentives to limit general overuse of health care independent of evidence-based standards; (2) applying evidence-based standards to cost sharing differentials to encourage greater use of services with higher clinical- and cost-effectiveness; and (3) limiting the total cost of coverage and thereby attracting more healthy persons to obtain voluntary insurance coverage.

c. *Accessible* – The EBS should be geographically accessible. To facilitate the development of EBS Certified Products, the accessibility standard should allow greater distances than current state criteria. This may include accommodations for service needs through telemedicine or other remote access methods, as necessary.

3. Scientific Evidence Emphasis

EBS Certified Products should provide distinct coverage levels for different services according to their status with respect to evidence-based clinical- and cost-effectiveness, and related benefit administration categories. For this purpose, "evidence" should include consideration of variations in the applicability of scientific studies based on demographic or other patient-specific variables.

a. *Evidence-Based Schedule of Services* – A higher than standard level of coverage should be provided for the majority of preventive services that research has determined to be highly clinically- and cost-effective, and that can be identified on the basis of a schedule of services and health care claim-based information. Example:

   - Primary evidence-based preventive services for children and adults that are highly recommended in scientific studies or guidelines should be covered at the highest level.

b. *Evidence-Based Programs and Networks* – A higher than standard level of coverage should be provided for the majority of services that research has determined to be highly clinically- and cost-effective, that cannot be identified through claim-based information but can be identified through specific programs, networks, or other methods that achieve clinically- or cost-effective outcomes. This would be accomplished by identification of effective programs or providers through the certification process (see recommendations #8-9), and members accessing the lowered cost sharing benefits tier through the specified programs or providers. The product could exclude from coverage entirely, or apply higher cost sharing to, services received from non-certified programs or providers. Evaluation of such programs, networks, or other methods should ensure that health plans have the necessary administrative systems in place. Examples of programs or networks that could qualify for higher than standard levels of coverage:

   - Diabetes treatment services highly recommended by and consistent with scientific studies or guidelines and provided through a designated provider network that achieves outcomes highly consistent with those standards.
   - Asthma treatment services highly recommend by and consistent with scientific studies or guidelines and provided through a disease management program that achieves outcomes highly consistent with those standards.
   - Hypertension treatment services highly recommended by and consistent with scientific studies or guidelines and provided through a medical home program that achieves outcomes highly consistent with those standards.
   - Mental health services highly recommended by and consistent with scientific studies or guidelines and provided through an integrated physical / mental health clinical support program that achieves outcomes highly consistent with those standards.

c. *Multiple Evidence-Based Options* – For services where multiple evidence-based options are available that are comparable in clinical- and cost-effectiveness, coverage should accommodate different options and consideration of patient preferences and values. Patients may be provided incentives to use provider networks that emphasize shared decision-making in which decision support systems are used to provide patients with

balanced information about treatment options, in a manner that allows them to arrive at informed, preference-based choices.

d. *Services With Limited or No Evidentiary Basis* – Many medical conditions have not been sufficiently studied or do not have research available to determine which treatment regimens are most effective. Compared to (a) and (b), a standard or lower level of coverage should be permitted for services where research has determined that evidence of clinical- and/or cost-effectiveness is equivocal or inadequate. For such services, coverage may also be designed to promote a generally more conservative practice approach appropriate to individual circumstances. A health plan may also elect to cover such services at the highest level.

e. *New Services With Premature Evidence* – For new services that are considered "promising" but for which evidence is not yet adequate to assess clinical- or cost-effectiveness, and for which any applicable FDA approvals have been granted, a standard or lower level of coverage compared to (a) and (b) should be permitted. Such coverage should be considered "provisional" and subject to the development of additional evidence through independently funded trials, at which time the service would be assigned to the applicable evidence-based category. To this end, all health plans offering EBS Certified Products should collaborate in a program to facilitate the development of evidence for, and a consistent approach to, coverage for new services with premature evidence. Patients electing to participate in clinical trials would do so with the knowledge that they may be assigned to the intervention or control (placebo) study group. This category does not include services at an earlier stage of assessment that are considered "experimental" or "investigative" (see Appendix C, "MCO Tools and Initiatives to Manage Costs Based on Service Value, Quality or Necessity"). Example:

   - The FDA has approved a new PET scan technology offering a higher resolution of scanning than is currently available in the market, but at significantly increased cost. There are currently no data to demonstrate that the new, increased resolution leads to improved health outcomes over and above existing technologies. The program described above would provide a means to cover such services on a provisional basis only as part of an independently funded, well-designed clinical trial coordinated through the collaborative evidence assessment program.

f. *Services Proven Clinically Ineffective* – Coverage should not be required for services that research has shown to be clinically ineffective or harmful. Example:

   - Arthroscopic surgery for osteoarthritis.
   - Autologous bone marrow transplantation with high-dose chemotherapy for end-stage breast cancer.

g. *Services Proven Not Cost-Effective* – Coverage should not be required for services that research has shown to be not cost-effective beyond the level of costs associated with the most efficient option. Example:

   - C-sections where the health of the baby or mother is not at risk in a vaginal delivery.
   - Services provided in an individual setting that can be provided more cost-effectively in a group setting.

- Services provided in a higher-cost facility (e.g., hospital inpatient or emergency room) that can be provided more cost-effectively in a lower-cost setting (e.g., hospital outpatient, clinic, or urgent care).

h. *Services Where Evidence Not Applicable to Benefit Design* – A standard level of coverage should be provided for types of services or circumstances for which it is not generally feasible to apply clinical- or cost-effectiveness criteria to health benefit design because there is limited or no opportunity to influence member behavior. (Note: this does not mean that there is no research applicable to such services, but that it is not practical to apply such research in the administration of an insurance product.) This does not preclude use of cost sharing as a standard incentive to encourage efficient use of such services. Examples:

- Medical emergencies.
- Urgent out-of-area services.

i. *Mandated Benefits* – The terms of coverage for services currently defined as "mandated benefits" should be the same as for any other services and based on the same scientific research standards.

4. Clinical Emphasis

EBS Certified Products should cover evidence-based clinical services directed primarily to the diagnosis and/or treatment of patients to assess, treat, cure, or prevent illness, injury, disability, disease, or related symptoms. Examples include services such as: chiropractic, emergency, home health, hospital, medical equipment and supplies, mental health, nursing home (non-custodial), physician / professional, prescription drugs, prevention, substance abuse, tests, therapies, transplants, and vision care. Subject to evidence, EBS Certified Products should also cover other promising clinical services for which evidence of clinical- and cost-effectiveness is emerging and related standards are in development, such as: clinically-based care and disease management, and patient-shared decision making services.

5. Current Market Structure Emphasis

EBS Certified Products should not be required to cover categories of services that are commonly excluded from standard health insurance policies. Examples:

- Dental services.
- Nursing home services (custodial).

6. Excluded Categories of Services

While the following types of services have value and may contribute to health, they are considered to be outside the scope of benefits for EBS Certified Products and should not be required to be covered. However, plans may offer coverage of such services at their discretion, or these services may be funded and arranged through other programs or mechanisms:

- *Long-Term Services and Supports* – Services directed primarily to maintaining a given level of health, capacity, or function over a long-term period, often combining clinical and non-clinical components. Examples:
  - Assisted living services.
  - Foster care services.
  - Nursing home (custodial) services.
  - Personal care services.
  - Respite care.
  - Targeted supports or "waiver" services.
- *Supportive Services* – Services that are not clinical but are indirectly related as supportive of overall health and/or enabling access to clinical services. Examples:
  - Interpreter services.
  - Housing assistance.
  - Income assistance.
  - Special diet needs (except as part of a recommended plan of care and where available only by prescription).
  - Transportation services (non-emergency).
- *Health Plan Activities* – Activities by health plans to promote access to and/or effective use of targeted clinical services. It should be noted that many of these types of activities are likely to be provided in connection with EBM programs and networks, as referenced in recommendation #3. Examples:
  - Care coordination services (distinct from clinic-based services)
  - Consumer education services.
  - Health promotion services.
  - Prevention reminders.
- *Self-Care Activities* – Activities by individuals to promote personal health and wellness. Examples:
  - Diet / nutrition (excepting clinically recommended diet needs available only by prescription).
  - Exercise.
  - Personal safety.
- *Population Health Factors* – General characteristics of society and/or the environment that have a significant effect on population health. Examples:
  - Education.
  - Employment.
  - Environment.

- Public safety.

- *Lifestyle Services* – Services provided primarily to enhance quality of life. Examples:
  - Hair transplants.
  - Cosmetic surgery.
  - Erectile dysfunction (without underlying pathology).

7. Principles for Service / Benefit Inclusion in EBS Coverage

Many core value commitments are implicit in the Work Group's recommendations, including fairness (e.g., mitigating health disparities), stewardship (e.g., cost-effectiveness), common good (e.g., promoting public health), and maximizing benefit and minimizing harm (e.g., clinical effectiveness). The Work Group recommends that the primary basis for service or benefit inclusion in the EBS should be evidence of clinical- and cost-effectiveness as described above. In cases where evidence is limited or unavailable, or where it is necessary to prioritize among effective services to meet a budget target (including through cost sharing design), the Work Group recommends that services be evaluated using a principle-based approach.

A detailed example of such an approach is shown in Appendix C, "Principles for EBS Service Inclusion." This framework provides for the evaluation of services based on several principles and related continua. Services that line up on the left side of the continua are more likely to be excluded and those primarily on the right side included, so long as the evidence is strong. Considering the strength of supporting evidence is also an important element of the evaluation procedure. Very few services will neatly line up on either side of the continua. For example, lack of population health benefit alone may not mean that a service should be excluded. A well proven, cost-effective service to treat a serious but rare condition could be covered, even though by definition the service and condition have no impact on population health. Protection from rare and high-cost events is at the heart of why people pool insurance funds. Conversely, a very common condition that is lower-cost may be less likely to be covered, unless early, inexpensive treatment can prevent a higher-cost outcome in the future.

8. EBS Maintenance Panel

A panel of health care system stakeholders should be appointed to provide ongoing oversight and maintenance of the EBS. The EBS Maintenance Panel should include representatives of health care consumers, health care providers, health plans, and employers. The panel would ensure that the evidence-based EBS criteria and principles are maintained, and that a buffer is provided from the political pressures that are sometimes associated with the historical "mandated benefits" approach. The responsibilities of the panel would include:

- Develop updates and refinements to the evidence-based criteria for EBS definition and service inclusion or exclusion, and related procedures and standards.
- Select organizations to provide technical assistance functions for EBS qualification and maintenance (see recommendation #9), and oversight of related deliverables and performance. Where applicable, the panel should arrange for technical assessment

functions related to scientific evidence status by utilizing existing qualified research and analysis organizations (e.g., ICSI, AHRQ) that are already engaged in similar activities.

- Identify specific definitions and accepted sources of clinically effective and clinically ineffective treatment regimens as discussed in recommendation #3.
- Identify evidence-based preventive services that should be covered (as discussed above in recommendation #3a). These primarily represent the types of services that can be readily incorporated directly into the benefit design at the service level and adjudicated by standard claim processing procedures.
- Provide specific guidance to health plans regarding how to quantify program and provider performance measures and incorporate such measures in EBS benefit designs to ensure uniform measures across plans for use by consumers and purchasers (as discussed above in recommendation #3b).
- Provide oversight and coordination of health plan collaboration to facilitate the development of evidence for, and a consistent approach to, coverage for new services with premature evidence (see recommendation #3e). The long-term goal for this collaborative is to generate, as quickly as possible, improvements in clinical outcomes through the use of evidence-based health care services while limiting overuse of services not determined to be evidence-based.
- Provide other assistance as necessary to the state agency charged to evaluate health insurance products for "EBS Certified" status (see recommendation #9).

9. EBS Qualification

A state agency should evaluate whether health insurance products meet the qualifications to be deemed "EBS Certified." Directly or through designated organizations, the agency should:

- Evaluate a health plan's implementation of the proposed EBS Certified Product design and provide certification if warranted. Provisional status as an EBS Certified Product may be granted in cases where it is not feasible for certain #3b services to demonstrate outcomes based on evidence-based standards, but where the proposed program or network is assessed to have a reasonable prospect for success. Continued status as an EBS Certified Product upon renewal would be dependent upon successful outcomes.
- Reassess EBS Certified Products at periodic intervals (e.g., 2-3 years) and recertify based on demonstrated continued fulfillment of requirements
- Develop methods for incorporating other state activities regarding quality and other measures into the EBS certification process (e.g., Minnesota Community Measurement).

Examples of EBS Certification

Product A meets the criteria of comprehensive and affordable coverage design (recommendation #2), and includes a $1,000 deductible. The deductible does not apply and 100% coverage is provided for a specified list of preventive services highly recommended in scientific studies (#3a), and for a broad range of services related to the treatment of chronic

conditions included in highly recommended evidence-based guidelines, when the services are provided through physicians selected on the basis of consistent adherence to those guidelines (#3b and #3c). Coverage is based upon the network or physician that the member selects, and not solely upon the service provided. Several different networks are designated for different chronic conditions, based on provider specialties. Services with limited or no basis in scientific studies, or for which evidence is not applicable, are subject to the deductible and covered at 80% (#3d, #3e and #3h). No coverage is provided for services proven to be clinically- or cost-ineffective (#3f and #3g). Product A also meets the coverage inclusion and exclusion criteria of recommendations #4, #5 and #6. Product A is approved for EBS Certified status.

Product B is similar to Product A, but for category #3b includes coverage only for two chronic conditions versus the services identified by the State Agency. Product B is not certified on the basis that it does not provide evidence-based coverage for a majority of services that research has determined to be highly clinically- and cost-effective, that cannot be identified through claim-based information but can be identified through other means for inclusion in a benefits design.

Product C is similar to Product A, but for category #3b proposes covering a broad provider networks with minimal distinction between clinically-effective services and those for which evidence shows low adherence to applicable evidence-based guidelines. Product C is not certified on the basis that it does not provide evidence-based coverage for a majority of services that research has determined to be highly clinically- and cost-effective, that cannot be identified through claim-based information but can be identified through other means for inclusion in a benefits design.

OTHER EBS MARKET RECOMMENDATIONS

10. Liability Protection

The Work Group recommends that health plans that offer EBS Certified Products should be protected against litigation related to excluding or limiting coverage of services; programs or providers consistent with the guidance provided by EBS Maintenance Panel or the state agency charged with EBS certification; or any of the requirements, standards, or allowances associated with EBS Certified status. The Work Group also recommends that, if feasible, protection against litigation be extended to health care providers operating within the framework of an EBS Certified Product for activities related to health care services based on scientific research of clinical- or cost-effectiveness.

11. Biased Selection Adjustment

The Work Group recommends that the Commissioner of Commerce should have authority to establish morbidity risk adjustment mechanisms or enrollment processes based upon morbidity in the private insurance market consistent with the EBS certification standards that are adopted. The Work Group believes that these conditions are less likely to arise in the current market than in a mandated coverage scenario (see recommendations #12-14 in following sections). The Work

Group also notes that there is a potential for health coverage becoming less affordable for some consumers if significant fund transfers among health plans are required as a result of a risk adjustment mechanism. Subject to these considerations, the Work Group recommends that the commissioner should trigger the biased selection adjustment mechanism if it is determined that morbidity-based selection impacts are creating significant market barriers to the development and marketing of EBS Certified Products. Example:

- Plan A establishes EBM networks and programs that are highly effective, and as a result attracts a disproportionate number of members with chronic conditions addressed by those programs.
- Plan B also maintains EBM networks and programs, but they are less effective and attract fewer members with chronic conditions.
- Plan A is at a competitive disadvantage because, even with effective EBM programs, its overall membership has significantly greater morbidity and associated costs than Plan B. Plan B can offer lower premiums because it incurs lower costs as a result of low average membership morbidity, even though its EBM programs are less effective.
- A biased selection adjustment based on comparative morbidity levels would require a risk adjustment surcharge to Plan B which takes into account its lower average morbidity compared to other insurance plans.

The Work Group is concerned with the potential for gaming by plans and other unintended consequences associated with establishing a transfer payment mechanism, and therefore recommends that a disease-specific certification approach not be adopted, and that sufficient flexibility in premium rating methodologies be allowed.

MANDATED COVERAGE SCENARIO

Recommendations #1-11 and the recommendations in this section (#12-13) are all applicable to a future coverage scenario in which some type of individual coverage requirement is established as part of a universal coverage program, and are based on the following assumptions:

- The EBS Certified Product standard will be used to determine which coverage qualifies for the purposes of the individual coverage requirement. Only EBS Certified Products will be considered to fulfill the individual coverage requirement.
- There continues to be a private market for health insurance, including competition based on price.
- Programs such as Medicaid and MinnesotaCare will continue to be available, and premium subsidies will be available in the private health insurance market to ensure affordability of health insurance coverage based on income. Policymakers may elect to expand the criteria for coverage comprehensiveness, affordability, and accessibility in the context of a universal coverage program and associated subsidies (see recommendation #2).

12. ROI Period and Scope

The Work Group recommends that the EBS Certified Product standards of comprehensive, affordable, and accessible coverage (recommendation #2) should be expanded to incorporate a long-term ROI period consistent with population health goals, rather than the shorter-term ROI period that may currently be required to some degree by insurance market conditions. This may include limited additions to (and not reductions from) the scope of coverage for services that are demonstrated to make a significant contribution to population health and are well supported by cost-efficiency evidence, and not supported exclusively by secondary considerations such as productivity gains. For services added based on this standard (e.g., using Quality Adjusted Life Year or "QALY" or comparable measures), consideration should also be given to providing such services through public health or other programs separate from the EBS. Example:

- Step 1. A qualified research organization conducts studies that identify a limited number of health services for which there are direct and substantial benefits to population health over the long term based on the measure.
- Step 2. A qualified research organization studies those high-QALY services to determine which would be most efficiently funded and delivered through: (a) public health programs and institutions, or (b) EBS Certified Health Plans.
- Step 3. The definition of *comprehensive* and *affordable* coverage is expanded to require inclusion of high-QALY services that would be most efficiently funded and delivered through EBS Certified Health Plans. Prospective or renewing EBS Certified Products are required to meet this standard in addition to other applicable requirements.

13. EBS Price Differentials

There are two financial mechanisms available to incentivize insured members to use clinical- and cost-effective treatments: cost sharing and premium differentials. Recommendations regarding the EBS have been primarily put in the context of differential in member cost sharing. However, premium differentials have some advantages over cost sharing for application in the EBS. Under one scenario, the reduction in member cost sharing would reflect the actual value of savings related to improved health outcomes and avoidance of unnecessary service. However, if this differential is not substantial enough, a patient may disregard the cost sharing differential. A lack of available service price information and knowledge on the part of the patient regarding clinical appropriateness further complicates this incentive.

On the other hand, if the cost sharing differential is larger than the value of the potential savings, members that utilize providers who are not EBS certified may be less costly to the health plan than members who do. This would result in an incentive for the health plan to encourage use of non-certified providers in order to lower overall plan premiums.

These issues are not important in the scenario where non-certified providers are entirely excluded from the coverage design. The following provides examples:

- Plan A covers services highly recommended in scientific evidence and guidelines as clinically- and cost-effective at 100% with no deductible (1st tier), and other eligible services at 80% with a $1,000 deductible (2nd tier). For conditions that are subject to

evidence, 75% of the Plan A members obtain the associated services through a designated evidence-based program or provider panel (1st tier). The remaining 25% obtain services for their evidence-based conditions outside the designated program or panel and incur the associated higher cost sharing (2nd tier). The average premium for Plan A is $400 per month.

- Plan B has a similar structure to Plan A, but only 25% of its members obtain services for evidence-based conditions through a designated program or panel (1st tier). The remaining 75% obtain services for their evidence-based conditions outside the designated program or panel and incur the associated higher cost sharing (2nd tier).
- Plan A incurs short-term savings associated with its members' higher adherence to evidence-based standards – e.g., 5%. Plan B incurs short-term savings associated with its members' higher utilization of services through 2nd tier coverage, which the plan reimburses at a lower rate because of the greater member cost sharing – e.g., 10%. If, as in this example, the short-term savings realized by Plan B are greater than the savings realized by Plan A, then Plan B will be able to offer lower premiums than Plan A. In this scenario, Plan A will be at a competitive disadvantage even though it applies evidence-based standards more effectively. This has been accomplished via passing significantly more expense to the patient through cost sharing at the time of service.

As a result, it may be more desirable to utilize a benefit design structure that doesn't differentiate between member cost sharing related to EBS certified services, but instead employs a premium differential. This allows for the decision regarding the use of EBS providers to be made at the time of purchase of insurance rather than at the time of treatment by the patient.

The Work Group recommends that the Commissioner of Commerce should have authority to evaluate the cost sharing and premium differentials as part of Commerce's normal rate review process. The Commissioner should trigger the EBS price differentials adjustment mechanism if it is determined that different rates of adherence are creating significant market barriers for EBS Certified Products that are more effective in promoting evidence-based services.

ISSUES TO ADDRESS SEPARATELY FROM EBS

14. Problems Best Handled Outside the EBS

The Work Group considers that the following issues create potential pressure on essential benefit design, and recommends that they should be handled through other initiatives:

- General affordability – The problem of unaffordable health insurance cannot be solved by adding more benefits to the EBS. For the price of health care services subject to overuse, consumers should pay for more of the cost of the services out of their own pockets. The cost of overused services will fall only when demand for the services falls. The cost of rare and expensive services is handled best by increased (risk-adjusted) price competition among health plans. Health plans that compete on the basis of price have an incentive to drive the price of those services down to marginal cost because those services are an important part of the premium.

- Lack of affordability for some subpopulations – If some subpopulations have trouble getting to the doctor, the solution is not to require all health insurance products to offer a transportation benefit, since that creates a tax (deductibility) subsidized service for all Minnesotans, including persons with high income. The preferred solution would be to provide targeted transportation subsidies specifically to people who cannot otherwise afford transportation to their doctor.
- Services that are important but should be paid for in other ways – For example, are health plans or public and private school systems the best delivery site for childhood hearing screenings? Before adding the cost of more services into the health insurance premium, careful thought should be given to the optimal delivery system for the service.

Appendices

The following appendices provide further background, resources and context for the report's conclusions and recommendations listed above and include the following sections:

Appendix A – A description of the Consulting Team.

Appendix B – A selection of noteworthy background research articles.

Appendix C – A selection of noteworthy handouts and discussion documents from Work Group meetings.

Appendix D – A summary of public input considered by the Work Group during their deliberations.

Appendix E – A copy of Minnesota Statute 62U.08 and the MDH EBS Work Group Charge.

APPENDIX A. CONSULTING TEAM

The lead consultant engaged for this project was Cirdan Health Systems and Consulting (Cirdan), with significant additional support from its subcontractor, the Minnesota Center for Health Care Ethics (MCHCE). Cirdan staff led presentations and research materials most closely related to insurance costs, benefit design, market operations, and practical examples or models of value-based coverage. MCHCE staff led group facilitation, structured decision-making, and presentations and research materials most closely related to health services and health policy research.

Cirdan is a health care consulting and information systems firm incorporated in 2001 in the State of Minnesota and located in downtown St. Paul. Cirdan's 19 employees provide clients with advice and support regarding health care finance, actuarial analysis, reporting system development, and strategic planning issues. Cirdan's clients include health plans, state and local government agencies, health care providers, employers, and unions. Cirdan staff leading the project and their project roles included:

- John Klein, MM, Project Manager
- Mike Rieth, FSA, MAAA, Lead Consultant
- John Stiglich, ASA, MAAA, Lead Actuary

MCHCE is a 501(c)3 non-profit organization based in St. Paul. Its staff and associates provide leadership in health care ethics for its sponsoring organizations and the communities they serve, as well as other local and national organizations. Staff are active members of clinical and organizational ethics committees and institutional review boards as well as various task forces and working groups. They participate in ethics consultations, assist with policy development, develop conferences and lecture series, lead community forums, and offer formal presentations to a wide variety of professional and community audiences. MCHCE staff and their project roles included:

- J. Eline (Ellie) Garrett, JD, Lead, Facilitation and Health Policy Analysis Team
- Karen Gervais, PhD, Facilitation and Health Policy Analysis Team
- Dorothy Vawter, PhD, Facilitation and Health Policy Analysis Team
- Angela Morley, JD, Project Assistant

APPENDIX B. BACKGROUND RESEARCH HIGHLIGHTS

During the initial stages of the project, the Consulting Team synthesized a large amount of relevant research within the Background Paper that focused primarily on development and use of scientific evidence and value-based concepts in insurance design. A selected sample of that research can be found below. Each item includes the title, author, a brief summary, and a hyperlink to the article.

- The Essential Benefit Package – Recommendations of the Oregon Health Fund Board of Benefits Committee

  Oregon Health Fund Board. (2008).
  http://www.oregon.gov/OHPPR/HFB/docs/BenefitCommitteeFinal.pdf

  A detailed summary is included in the Case Studies section above. Additional information can be found
  here:http://www.oregon.gov/OHPPR/docs/HealthReformResourcesDocs/POLICY_BRIEF_Essential_Benefit_Package_Color_031709.pdf

- Value-Based Insurance Design

  American Academy of Actuaries: Health Care Quality Work Group. (2009, June). *Issue Brief.*
  http://www.actuary.org/pdf/health/vbid_june09.pdf

  This issue brief defines value-based insurance design (VBID), provides an overview of its prevalence, examines the barriers to implementation, and reviews policy considerations related to VBID adoption and implementation. One key point is that VBID is still evolving, but it can be part of a broader effort to better align financial incentives with improvements in value and quality of care. There are a number of issues policymakers should address as they consider whether and how to include VBID as part of health reform including, among others, initial costs, administrative costs, data challenges, and barriers to personalization. Additionally, if benefit package requirements are included as part of insurance market reforms, the requirements should be flexible enough to allow for VBID. Policymakers can also help facilitate the implementation of VBID by financing comparative effectiveness research (CER) and by supporting improvements to health care information infrastructure.

- Comparative Effectiveness Research

  American Academy of Actuaries: Health Care Quality Work Group. (2008, Sept). *Issue Brief.*
  http://www.actuary.org/pdf/health/comparative.pdf

This issue brief discusses current assessments of health care quality within the U.S. It reviews the typical process for incorporating new treatment protocols and technologies into health insurance coverage, both commercially and in government programs. It reviews policy implications of CER and stresses the need to review both new and existing treatments and technologies. The brief suggests that CER can add more value if it goes beyond proving that a treatment is safe and effective to including head-to-head trials that compare treatments and technologies. Additionally, it could provide value by assisting in determining which patients respond better to specific treatments. Finally, the brief notes that the ultimate value of CER depends on its ability to positively influence treatment decisions, not just insurance and reimbursement decisions. Insurance design and reimbursement policies can influence treatment by favoring those treatments deemed most clinically- and cost-effective.

- Value-Based Insurance Design Landscape Digest

  Fendrick, A.M. (2009, July). Center for Value-Based Insurance Design, University of Michigan.
  http://www.sph.umich.edu/vbidcenter/pdfs/NPC_VBIDreport_7-22-09.pdf

  This article/digest presents a very complete description of VBID and is the basis for much of the discussion included in the Background Paper. It contains a thorough description of alternative approaches, financial impacts, barriers and other implementation considerations, case studies, and synergies with other reform efforts. The author and the Center take a strong but well-supported advocacy position for VBID. Note that the University of Michigan's Center for Value-Based Insurance Design is funded in part by the National Pharmaceutical Council.

- A Model for Improving Coverage Policy Decisions

  Priester, R., Gervais, K.G., & Vawter, D.E. (1999). *The American Journal of Managed Care.* 5 (8), 981-91.
  http://www.ajmc.com/issue/managed-care/1999/1999-08-vol5-n8

  This article, co-authored by two of the professionals involved with the Work Group's efforts through the Minnesota Center for Health Care Ethics, asserts that reasoned and defensible coverage decisions are essential for a fairer and more efficient health care system. Because health care resources are finite, coverage decisions should be informed by economic evaluations and made from a perspective that attends to the interests of both individuals and the entire population enrolled in a plan as a whole. Coverage decisions for all health care interventions should follow a two-step procedure that consists of: (1) the relatively impartial and objective assessment of an intervention's eligibility for coverage; and (2) the distinctively value-laden determination (for which the enrolled population's values and preferences should take priority) to cover, conditionally cover, or not cover an intervention.

APPENDIX C. SELECTED WORK GROUP DISCUSSION DOCUMENTS

Appendix B includes the following documents that were discussed in one or more Work Group meetings:

Title	Work Group Meeting(s)
MCO Tools and Initiatives to Manage Costs Based on Service Value, Quality or Necessity	Meeting #3
ICSI Guidelines List	Meeting #3
Principles for EBS Service Inclusions	Meetings #1 and #4

MCO Tools and Initiatives to Manage Costs Based on Service Value, Quality or Necessity
Meeting 3 (9/23/09) – Handout J (revised based on meeting feedback/discussion)

Many elements of current benefit design and managed care operations can also be viewed as supporting EBS principles either directly or indirectly. The following is a partial list:

TOOL OR INITIATIVE	DESCRIPTION	EBS CONNECTION
Benefit Exceptions	Health plans make exceptions in some cases to expand standard coverage where the additional benefit is clinically indicated for a specific patient and cost-effective.	Case specific application of clinical and cost-effectiveness judgments
Claim Edits	Claim edits are programmed filters applied at the time of adjudication. For example, edits may identify claims using improper service/diagnosis combinations (e.g., a surgery without any suitable diagnosis) or service/gender combinations (e.g., a female procedure for a male). Such claims may be associated with provider data entry omissions or errors, or actual inappropriate services.	One basic way to limit payment for services that are not appropriate or "low value."
Coverage with "Evidence in Development"	For certain new services or technologies for which evidence is not yet available, plans periodically allow for coverage if the patient agrees to participate in a clinical trial. This improves evidence and leads to more informed decisions on the coverage.	Supports the development of evidence to allow for a grounded coverage decision to be made.
Disease Management	Members may be requested to enroll in a disease management (DM) program to support them in self-care education and guideline adherence for their specific condition(s). Participation in the DM program may then be tied to coverage of and/or lower cost sharing for services encompassed within the applicable guideline.	Enrollment in a DM program may be a proxy in claims adjudication for more complex guideline adherence logic.
Experimental Status	Health insurance policies commonly exclude services that are considered "experimental" or "investigative" because there is not yet sufficient evidence to support their clinical effectiveness. Some experimental procedures may later to be proven to be effective, while others are not.	Applies a minimum standard or evidence of effectiveness and safety for services to be covered.
Health Assessments	Health plans may request members to complete health assessments at enrollment or other times. Assessments may assist in identifying candidates for DM programs, serve as a baseline for measuring changes in health status, or otherwise support outreach and self-care supports.	May support DM programs or other initiatives to communicate and tailor guidelines.
Mandated Benefits	Certain services or service/diagnosis combinations have been deemed to be of sufficient importance or value to mandate inclusion in all health insurance policies. (See the Minnesota list of required benefits.) Mandates generally require full coverage and do not provide for cost-sharing variations.	Consistent with the "Services" or "Services + Condition" EBS design approaches.

TOOL OR INITIATIVE	DESCRIPTION	EBS CONNECTION
Medical Necessity	The standard of "medical necessity is a fundamental component of most health insurance policies. It is based on a legal doctrine related to activities which are justified as reasonable, necessary, and/or appropriate based on evidence-based clinical standards of care. Services that are not medically necessary are not covered. Within the insurance mechanism, this definition serves to exclude from coverage numerous serves that may otherwise be considered of low value in an EBS design.	Services that may be ranked as limited or no value from an EBS standard may also fail to meet current "medical necessity" standards.
Provider Panels/ Cost-Sharing Tiers	In-depth evaluation of health care provider practice patterns may be used to identify providers whose overall methods of practice most closely correspond to evidence-based standards, guidelines, or other applicable criteria. Such providers may then be designated for inclusion in a panel or network that is communicated to members, with the expectation that most (if not all) services received will be more likely to correspond to EBM criteria.	Use of providers recognized as practicing consistent with EBM may be a proxy in claims adjudication for more complex guideline adherence logic.
Quality Information to Consumers, Providers	Educating consumers and providers on which services, technologies and drugs offer the best value may influence purchasing decisions in favor of more conservative or evidence-based courses of treatment. This has become a more important area of health plan activity as more members are covered by high-deductible, consumer-directed coverage designs.	Information related to EBM standards and guidelines is important to promote understanding and adherence.
Service Authorizations	Requiring prior authorization for some services allows the health plan to validate that the service, as it is proposed to be used in a given situation, adheres to guidelines and therefore should be covered. Prior authorizations are most feasible for services that are elective or can be scheduled in advance. Concurrent notification and authorizations are also applicable for other services such as certain hospital stays, and may affect authorized length-of-stay or discharge planning. Authorizations may be based on accepted guidelines, the judgment of the health plan medical director, or other factors.	Authorizations allow the application of medical necessity standards and judgments to ensure that the proposed services are of reasonable value.
Service Limits	Limits on the number of services, visits, or days allowed during a calendar period are sometimes based on over-utilization concerns in areas of practice where medical necessity or effectiveness can be more difficult to confirm. Examples have included: mental health, chemical dependency, chiropractic, physical therapy.	Within the context of the EBS design, may limit potential over-use and therefore lower-value services.

ICSI Guidelines List
Meeting 3 (09/23/2009) – Handout K
(from www.icsi.org)

Health Care Redesign

- Baskets of Care
  ICSI is facilitating a Minnesota Department of Health project that is defining seven baskets of care meant to help consumers compare the value of services offered by different providers.
- Diagnostic Imaging

ICSI is working with the medical community to enable providers to use appropriateness criteria to order high-technology diagnostic imaging procedures at the point of service as an alternative to health plan prior notification requirements.

- DIAMOND
  DIAMOND is one of the nation's most promising efforts to improve health care for people with depression because it changes the way care is delivered and how it is paid for. Through ICSI, medical groups, health plans, employers and patients collaborated to develop a better, evidenced-based model for managing depression.
- Health Care Home

"Health Care home" is considered a key strategy to transform health care. ICSI is collaborating with health care leaders to build a medical home model that is patient-centered and value-driven.

Behavioral Health

Guidelines

1. ADHD, Attention Deficit Hyperactivity Disorder in Primary Care for Children and Adolescents (Guideline)
2. Depression, Major, in Adults in Primary Care (Guideline)

Selected ICSI Resources

- Understanding Anxiety and Panic Attacks, by Park Nicollet Health Services (brochure)
  Released 07/2007

Cardiovascular

Guidelines

3. ACS: Chest Pain and Acute Coronary Syndrome, Diagnosis and Treatment of (Guideline)
4. Antithrombotic Therapy Supplement (Guideline)
5. Atrial Fibrillation (Guideline)
6. Coronary Artery Disease, Stable (Guideline)
7. Heart Failure in Adults (Guideline)
8. Hypertension Diagnosis and Treatment (Guideline)
9. Lipid Management in Adults (Guideline)
10. Stroke, Ischemic, Diagnosis and Initial Treatment of (Guideline)
11. Venous Thromboembolism Diagnosis and Treatment (Guideline)
12. Venous Thromboembolism Prophylaxis (Guideline)

Selected ICSI Resources

- ACS: Acute Coronary Syndrome, Admission to CCU for (Order Set)
- Heart Failure, Admission for (Order Set)
- Heart Failure, Discharge for (Order Set)
- Heart Failure, Emergent Orders for (Order Set)
- Stroke for Patient not Receiving tPA, Ischemic; Admission for (Order Set)
- Stroke for Patients Receiving tPA, Ischemic; Admission for (Order Set)
- Venous Thromboembolism Prophylaxis (Order Set)

Musculo-Skeletal Disorders

Guidelines

13. Low Back Pain, Adult (Guideline)
14. Pain, Acute, Assessment and Management of (Guideline)
15. Pain, Chronic; Assessment and Management of (Guideline)

Patient Safety & Reliability

Guidelines

- There are currently no Patient Safety & Reliability Guidelines.

Protocols

- Falls (Acute Care), Prevention of (Protocol)
- Perioperative (Protocol)
- Pressure Ulcer Treatment (Protocol)
- Pressure Ulcers, Skin Safety Protocol: Risk and Assessment of (Protocol)
- Rapid Response Team (Protocol)
- Retained Foreign Objects During Vaginal Deliveries, Prevention of Unintentionally (Protocol)
- Safe Site Invasive Procedure – Non-Operating Room (Protocol)

Selected ICSI Resources

- Falls (Acute Care), Prevention of (Protocol)
- Pressure Ulcer Treatment (Protocol)
  - Pressure Ulcers, Skin Safety Protocol: Risk and Assessment of (Protocol)
  - Rapid Response Team (Protocol)
  - Retained Foreign Objects During Vaginal Deliveries, Prevention of Unintentionally (Protocol)
  - Safe Site Invasive Procedure – Non-Operating Room (Protocol)
  - Perioperative (Protocol)

Preventive & Health Maintenance

Guidelines

16. Chronic Disease, Primary Prevention of (Guideline)
17. Colorectal Cancer Screening (Guideline)
18. Immunizations (Guideline)
19. Obesity, Prevention and Management of (Mature Adolescents and Adults) (Guideline)

20. Preventive Services for Adults (Guideline)
21. Preventive Services for Children and Adolescents (Guideline)

Respiratory Disease

Guidelines

22. Asthma, Diagnosis and Management of (Guideline)
23. Chronic Obstructive Pulmonary Disease (COPD), Diagnosis and Management of (Guideline)
24. Otitis Media in Children, Diagnosis and Treatment of (Guideline)
25. Respiratory Illness in Children and Adults, Diagnosis and Treatment of (Guideline)
26. Sleep Apnea, Diagnosis and Treatment of Obstructive (Guideline)

Selected ICSI Resources

- Asthma, Admission for (Order Set)
- Pneumonia, Ventilator-Associated, Prevention of (Order Set)

Women's Health

Guidelines

27. Breast Disease, Diagnosis of (Guideline)
28. Cervical Cytology (Pap Smear) and HPV Testing, Initial Management of Abnormal (Guideline)
29. Labor, Management of (Guideline)
30. Menopause and Hormone Therapy (HT): Collaborative Decision-Making and Management (Guideline)
31. Osteoporosis, Diagnosis and Treatment of (Guideline)
32. Prenatal Care, Routine (Guideline)

Selected ICSI Resources

- Admission for Routine Labor (Order Set)

Other Health Care Conditions

Guidelines

33. Diabetes Mellitus in Adults, Type 2; Diagnosis and Management of (Guideline)
34. Headache, Diagnosis and Treatment of (Guideline)
35. Palliative Care (Guideline)
36. Preoperative Evaluation (Guideline)

Selected ICSI Resources

- Insulin Management, Subcutaneous (Order Set)
- Palliative Care (Order Set)

Patient & Family Guidelines

37. Acne Management
38. ADHD: Attention Deficit Hyperactivity Disorder in Primary Care, Diagnosis and Management of
39. Breast Disease, Diagnosis of
40. Colorectal Cancer Screening
41. COPD: Chronic Obstructive Pulmonary Disease

42. Coronary Artery Disease, Stable (for patient & families)
43. Depression In Adults In Primary Care, Major
44. Diabetes Mellitus, Type 2
45. Headache, Diagnosis and Treatment of
46. Heart Failure in Adults
47. Hypertension Diagnosis and Treatment
48. Lipid Management in Adults
49. Low Back Pain, Adult
50. Menopause and Hormone Therapy (HT): Collaborative Decision-Making and Management
51. Obesity (Mature Adolescents and Adults), Prevention & Management of
52. Osteoporosis, Diagnosis and Treatment of
53. Pain, Chronic, Assessment and Management of
54. Palliative Care
55. Prenatal Care, Routine
56. Preventive Services for Adults
57. Preventive Services for Children and Adolescents
58. Tobacco Use Prevention and Cessation for Adults
59. Tobacco Use Prevention and Cessation for Children

PRINCIPLES FOR EBS SERVICE INCLUSION[7]

Meetings 1 (9/9/09) and 4 (10/2/09) – with refinements based on Work Group discussion

Criterion	Continuum		
Assessment of the condition to which the health service pertains			
Size of the population affected	Small	Medium	Large
Level of health disparities among affected sub-population	Low	Moderate	High
Seriousness of condition	Minor	Moderate	Serious

				Evidence				
Expected effect of health service				None or N/A	Weak	Incon-clusive	Mod-erate	Strong
Proportion of affected population that can be reached with the service	Small	Medium	High					
Health benefit (importance)	Low	Moderate	High					
Probability of benefit	Low	Moderate	High					
Duration of benefit (how long will the benefit last)	Short	Moderate	Long Term					
Not conservative vs. conservative	Not conserv-ative	Moderate	Conserv-ative					
Cost	Expensive	Moderate	Inexpen-sive					
Relative clinical effectiveness (compared to competing service)	Less effective	Same	More effective					
Relative cost (compared to competing service)	More costly	Same	Less costly					
Secondary benefits (e.g., productivity)	None/ unim-portant	Some	Many / important					

Additional considerations (not on a continuum)	
When is the health benefit most evident?	▪ Soon ▪ In a few years ▪ Far in the future
Nature of benefit (circle one or more)	▪ Diagnosis ▪ Symptom relief ▪ Functional improvement ▪ Cure ▪ Secondary prevention ▪ Primary prevention

[7] The decision-making criteria are adapted from a framework described in Priester R, Gervais KG, Vawter DE. A model for improving coverage policy decisions. (1999) *Am J Manag Care* 5(8):981-91.

Notes for use of the service assessment principles framework

The criteria offered in the table are not intended as a rigid algorithm, but as a framework to guide selected EBS decision-making by health plans (in the current market) or by a public agency or panel (in a universal coverage scenario) for services that are not clearly demonstrated as clinically- or cost-effective. In using the framework, it is likely that the majority of services will end up in various constellations in the middle of the continua and with different degrees of supporting evidence for each of the continua. In general, similar coverage decisions should be made for similar constellations of responses on the table.

The two additional considerations at the bottom of the table are offered for different reasons. The question about timing of health benefit is raised so that the issue of potential long-term benefit will not be ignored. Presumably, a health plan would need little urging or reminder to cover services that will pay off quickly in terms of better health. The Work Group stresses that long-term benefit should also be considered; without asking the question explicitly it is possible that long-term benefit might be overlooked.

Finally, the framework also asks about the nature of the service, i.e., whether it is intended to provide symptom relief, functional improvement, cure, secondary prevention, or primary prevention. The nature of health benefit can be relevant in at least two ways:

1. First, services with similar intended goals for the same condition could be compared against each other (e.g., two competing services both intended to provide symptom relief or functional improvement). Services with dissimilar goals may be less appropriately compared (prevention vs. cure), because each of the goals may be important to different groups of patients at different ages and states of disease.
2. Second, the nature of benefit can be relevant in deciding whether a cost-sharing incentive is necessary and appropriate. Presumably patients would not need to be incented to seek cures, functional improvement or symptom relief if the condition they are suffering is serious. Primary and secondary prevention, though, are often appropriately the subject of cost-sharing incentives.

Reasonable people may come to different decisions when applying the decision-making criteria. Thus, for circumstances where it is appropriate to use this framework, the process for applying the decision-making is as important as the criteria themselves and should be: open and transparent, accountable, made by a body that includes representatives of the persons who are covered under the plan, and subject to a reasonable review process.

APPENDIX D. SUMMARY OF PUBLIC INPUT

The following lists public input received by MDH in order of date of receipt as indicated by the designated numbers. Work Group members received complete public input submission information via emails. The summaries list whether evidence was also provided. While the consulting team reviewed all submissions for content, given the volume of submissions and supporting documentation, they did not review the quality of the evidence. The summary descriptions are provided by the consultants and were intended to assist Work Group members in locating topics and seeing the breadth of comments, and were not reviewed or approved by the submitters. While the consultants sought to summarize the input as accurately as possible, it is possible that the summaries may not fully reflect the intent of the submitter. The original submission, rather than the summary, should be the basis for any official attribution.

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1. Floyd Anderson, MD, Chair - Private Practice Committee, Minnesota Psychiatric Society, Clinical Associate Professor, University of Minnesota.

- Expresses support for serious and persistent mental illness psychiatric case management/network therapy.
- Points to the need for higher reimbursement and a billing code.
- No specific evidence provided.

2. Susan Lane, MN Better Birth Coalition

- Support for Milbank Reform States Group "Evidence Based Maternity Care"
- Support for universal doula care for birthing women.
  - Women who have a doula have up to 50% fewer cesarean sections.
  - Babies of high risk women supported by a doula prenatally have better birth weights and fewer NICU admissions.
  - Doula support has been proven to decrease rates of PPD.
  - MN women have a statutory right to doula care.
- Supporting evidence cited.

3. Robert W. Geist MD, East Metro Medical Society

Discussion of various topics he would like Work Group members to consider in their deliberations, selected comments include:

- Benefits sets are all very comprehensive, it's price that varies by policies.
- Full coverage is often confused for "pre-paid everything".
- Income level affects the true level of a catastrophe for a given individual.
- If the price of benefits is set by state managers (setting the benefits is the least of what they do), the authorities must set the price of services and control access.
- Do not confuse benefit sets with the degree of access, the latter of which depends on premium price.
- Discussion does not cover specific benefits, so no evidence is provided.

4. Rachel Callanan, American Heart Association

- Support for preventive cardiovascular services. Submission includes a list of specific services.
- Insurers should update their coverage of preventive services annually to reflect substantive changes in the evidence.
- A broad range of authoritative documents should be used including the United States Preventive Services Task Force's "Guidelines to Clinical Preventive Services," the Partnership for Prevention's "Rankings of Preventive Services for the U.S. Population" and pertinent AHA publications.
- Insurers should eliminate all cost sharing for evidence-based preventive cardiovascular services that are proven to be of substantial benefit.
- Supporting evidence cited.

5. Trisha A. Stark, Ph.D., LP, Minnesota Psychological Association

- Support for a full complement of evidence-based psychotherapeutic and psychosocial mental health interventions.
- The increase in cost for mental health services has not mirrored the growth in health care more generally.
- Like with medical care, it's cost effective to focus on those with chronic conditions.
- A Medicaid population study found that after one year it was cost-effective to expand MH problem resolution therapy targeted toward the highest utilizers of medical care.
- McDonnell-Douglas Corporation saved $4.00 in health costs, absenteeism, and attrition for every $1.00 spent on the in-house counseling.
- Supporting evidence provided for a variety of treatments types based on diagnosis and services, all of the research papers cite treatments meeting the ICSI Grades I / II.

6. Benjamin H. Whitten, MD, Minnesota Medical Association

- Supports universal coverage of essential benefits for every Minnesotan.
- Key principals for inclusion/exclusion of benefits:
  - Floor of coverage for effective care
  - Encourage routine care and early diagnosis, not just catastrophic protection
  - Cover behavioral health the same as other health
  - Coverage for clinical trials
  - No coverage for class III (contraindicated) in clinical trials
  - EBS should eliminate coverage mandates.
- With regard to cost sharing:
  - Standardize cost sharing – copays and deductibles
  - No cost sharing for immunization, primary care, care coordination in medical homes.
- The letter does not get into detail about benefit considerations, hence no supporting evidence is provided.

7. Ann Wendling on behalf of the Minnesota Cancer Alliance

11. David Willoughby, ClearWay Minnesota

- Support for including tobacco cessation benefits:
  - Smokers incur more medical costs and are less productive.
  - Smoking causes disease and pregnancy complications.
- Tobacco use treatment doubles quitting success rates – counseling and medication.
- Includes a recommended list of covered benefits.
- Supporting evidence cited.

8. Jim Meffert-Nelson, Minnesota Optometric Association

- Support for including eye and vision care services.
- Healthy eyes and clear vision play important role in the education of our children.
- Healthy eyes and clear vision are critical to getting jobs for people on public programs.
- An Optometric Clinical Practice Guideline developed by the American Optometric Association for a "Comprehensive Adult Eye and Vision Examination" was provided.
- The guideline includes references to supporting articles and evidence.

9. Steve Larson, Consortium for Citizens with Disabilities; John Tschida, Courage Center; and Anne L. Henry, Minnesota Disability Law Center.

13. Linda Kelley, Sister Kenny Rehabilitation Institute

- Support for the EBS to specifically and intentionally include persons with long-term, significant or permanent disabilities.
- They support comprehensive services for Minnesotans with disabilities and chronic conditions.
- They would like the EBS to address affordability and eliminate required impoverishment in order to qualify for Medical Assistance.
- They have concerns that too high of an evidence standard could result in excluding services needed for people with disabilities, since they often are based on clinical effectiveness.
- They note that while they support EBM for persons with disabilities, it is in short supply.

10. Stephanie Heim, Minnesota Dietetic Association

- Support for inclusion of Medical Nutrition Therapy.
- Inclusion of nutrition intervention and counseling provided by a registered dietitian as part of a healthcare team results in significant improvements in weight and BMI, HgBA1C, blood pressure, and serum lipids.
- Studies confirm that MNT resulted in improved clinical outcomes and reduced costs related to physician time, medication use, and/or hospital admissions for people with obesity, diabetes, and disorders of lipid metabolism, as well as other chronic diseases.
- Seeks consideration for waiving deductibles and other fees for nutrition services.
- Links to supporting evidence included that cover both clinical and cost effectiveness and specific disease/conditions where appropriate.

12. Eileen M. Smith, Minnesota Council of Health Plans (MCHP) (the state's eight non-profit MCOs)

- Discussion of the goals for the EBS from the perspective of the MCHP.
- EBS is fundamentally looking at the services to be covered and where evidence does exist, using that evidence to determine the appropriate level of coverage for that service, including determining if state mandates are appropriately included in an essential benefit set. Therefore, MCHP encourages the Work Group to look at what is essential for any person, whether insured or uninsured.
- First identify a core set of essential services to be covered.
- Strongly encourage relying on national or community collaborative work, such as the ICSI, in technology assessment/comparative effectiveness, rather than developing a separate state-specific program of technology assessment/comparative effectiveness. Allows for alignment of local efforts with national efforts.
- Given the tight timelines, it might be more helpful to focus on general categories of services and coverage levels, rather than focusing too specifically on services. This more general approach allows for flexibility as science develops.
- The letter does not get into detail about benefit considerations, hence no supporting evidence is provided.

14. Matt Anderson, Minnesota Hospital Association

- Discussion of the purpose and goals for the EBS from the perspective of the MHA.
- Legislative intent of EBS is about defining what minimum insurance package an individual would have to obtain to fulfill a future individual mandate.
- MHA does not believe the Work Group's charge is to review existing mandated benefits to determine whether they are justified or appropriate. Don't "water down" coverage.
- Include coverage for services, treatments, and procedures that may not have significant evidence demonstrating their effectiveness.
- Avoid a static list of included or excluded benefits, and instead put forth a methodology for evaluating benefits in the future.
- The letter does not get into detail about benefit considerations, hence no supporting evidence is provided.

15. Peter Nelson, Center of the American Experiment

- Discussion of the purpose and goals for the EBS from the perspective of the CAE = "Keep it simple."
- Legislative intent was to identify the "minimum benefit set" that people require to "obtain necessary health care." Not to recommend "a private benefits set that encourages greater use of effective health care services and less use of ineffective or low-value health care services" as put forth by MDH.
- Elevating whether benefits are scientifically based and cost-effective to the primary purpose encourages the Work Group to go beyond its legislative mandate. Avoid CER, VBID, and L/M/H benefit options.

- Avoid getting too specific. Strive to define only broad categories of coverage—such as inpatient hospital and emergency care.
- The legislative directive focuses on encouraging enrollees to receive necessary health care services—specifically, services that enrollees need in order to avoid more expensive medical complications in the future. Not to be confused with paying for value.
- Cost sharing for necessary services should be eliminated. However, that should not preclude health plans from developing methods to offer their enrollees additional incentives to receive necessary care and to better manage the costs related to these services.
- Where Minnesota's current benefit mandates are not essential, give a full explanation for why.
- The letter does not get into detail about benefit considerations, hence no supporting evidence is provided.

16. Charles Sawyer, DC, Northwestern Health Sciences University on behalf of the Minnesota Chiropractic Association

- Support for inclusion of direct access to chiropractic services in the EBS.
- Spinal manipulation, when provided by doctors of chiropractic for the treatment of back and neck pain, should be classified by the Workgroup as a Tier 1 health care service with reduced enrollee cost.
- Chiropractic offices tend to have lower overhead and often are located in rural communities. May cost more to treat back/neck pain by medical physicians/PTs.
- Points to evidence of cost-effectiveness for use of chiropractic care as an initial option or as a step up from self-care options.
- Supporting evidence cited.

17. Chris Wiesemeyer, GlaxoSmithKline

- Support for VBID focus.
- Support for a long-term perspective and recognition of market failures that produce a short-term perspective.
- A number of comments on the handouts.
- The letter does not get into detail about benefit considerations, hence no supporting evidence is provided.

18. Richard J. Morris, M.D.

- Support for allergen immunotherapy.
- Cost-effective to include an allergy specialist in asthma care.
- Allergies (and asthma) are prevalent in the population, and allergen immunotherapy reduces absenteeism, improves symptoms and quality of life, and reduces medication costs.
- Links to supporting evidence are provided.

62U.08 ESSENTIAL BENEFIT SET.

Subdivision 1. **Work group created.**

The commissioner of health shall convene a work group to make recommendations on the design of a health benefit set that provides coverage for a broad range of services and technologies, is based on scientific evidence that the services and technologies are clinically effective and cost-effective, and provides lower enrollee cost sharing for services and technologies that have been determined to be cost-effective. The work group shall include representatives of health care providers, health plans, state agencies, and employers. Members of the work group must have expertise in standards for evidence-based care, benefit design and development, actuarial analysis, or knowledge relating to the analysis of the cost impact of coverage of specified benefits. The work group must meet at least once per year and at other times as necessary to make recommendations to the commissioner on updating the benefit set as necessary to ensure that the benefit set continues to be safe, effective, and scientifically based.

Subd. 2. **Duties.**

By October 15, 2009, the work group shall develop and submit to the commissioner an initial essential benefit set and design that includes coverage for a broad range of services, is based on scientific evidence that services are clinically effective and cost-effective, and provides lower enrollee cost sharing for services that have been determined to be cost-effective. The benefit set must include necessary evidence-based health care services, procedures, diagnostic tests, and technologies that are scientifically proven to be both clinically effective and cost-effective. In developing its recommendations, the work group may consult with the Institute for Clinical Systems Improvement (ICSI) to assemble existing scientifically based practice standards.

Subd. 3. **Report.**

By January 15, 2010, the commissioner shall report the recommendations of the work group to the chairs and ranking minority members of the legislative committees and divisions with jurisdiction over health care policy and finance.

History: *2008 c 358 art 4 s 11*

MDH – Essential Benefit Set Work Group Charge

Background:

Minnesota Statutes 62U.08 requires the Commissioner of Health to convene a Work Group to make recommendations on the design of an "essential benefit set" that provides coverage for a broad range of services and technologies, is based on scientific evidence that the services and technologies are clinically effective and cost-effective, and provides lower enrollee cost sharing for services and technologies that have been determined to be cost-effective. The benefit set must include necessary evidence-based health care services, procedures, diagnostic tests, and technologies that are scientifically proven to be both clinically effective and cost-effective.

The primary purpose of the Work Group is to make a recommendation for a private insurance benefit set that encourages greater use of effective health care services and less use of ineffective or low-value health care services.

Essential Benefit Set Work Group Key Issues to be Addressed:

Essential Benefit Set Work Group members will provide advice on how to define an essential benefit set that meets the criteria laid out in Minnesota Statutes 62U.08. Members will consider and provide input on key issues that must be addressed in reaching this decision, including the following:

- What health care services should be included in the essential benefit set as covered benefits? Are there services that are not typically covered today by private insurance that should be included? Are there services that are typically covered today that should be excluded?
- What structure of enrollee cost sharing will optimize the use of effective care? For example, should deductibles or other cost-sharing requirements be waived for drugs or services that are deemed to be particularly important for managing chronic disease and containing health care cost growth over the long run?

Membership:

The Essential Benefit Set Work Group will include representatives of health care providers, health plans, state agencies, and employers. The law requires that members of the work group have expertise in at least one of the following:

- Standards for evidence-based care;
- Benefit design and development;
- Actuarial analysis; or
- Analysis of the cost impact of coverage of specified benefits.

The Work Group's meetings will be open to the public.

Timeline of Work Group Activities and Expectations for Members:

- Attend approximately six half-day meetings in September and October 2009.
- Review meeting materials ahead of meetings and be prepared to contribute clear and focused ideas for discussion.
- Maintain a statewide and system-wide perspective in generating recommendations about how to define an essential benefit set.
- Review and provide comment on a preliminary report to be shared with Work Group members by October 9, 2009.
- Contribute to the development of final recommendations to be submitted to the Minnesota Department of Health by October 31, 2009.

Deliverables:

This group will produce a final report providing recommendations on how to define an essential benefit set that meets the criteria defined in Minnesota Statutes 62U.08. The Work Group's report will identify three options for levels of coverage (high, medium, and low options). After the Work Group makes its recommendations, an actuarial analysis of the cost of the options will be completed.