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Policy Options for Processes to Determine Coverage Guidelines for the United States Preventive Services Task Force (USPSTF) Recommendations
National Business Group on Health[SM]

The U.S. Preventive Services Task Force (USPSTF, or "Task Force,") reviews the evidence for clinical preventive services and makes recommendations for clinical care. This memo reviews the functions and history of the USPSTF, including changes made by the Affordable Care Act (ACA); outlines issues that have arisen from the provisions in the ACA; and offers options for addressing those issues.

Background. The USPSTF is composed of 16 nongovernmental, volunteer members. They are appointed for four-year terms by the Director of the Agency for Healthcare Research and Quality (AHRQ). The Task Force is funded through AHRQ's appropriation; it received $5 million for FY10 (all from the Prevention and Public Health Fund (PPHF) and $7 million for FY11 (also all from the PPHF). In its FY12 budget justification, the administration stated that it would allocate $11.3 million to the Task Force, none from the PPHF[1].

The Task Force does not conduct research, but rather reviews and analyzes existing research. The initial review of evidence is conducted by one of fourteen Evidence-Based Practice Centers (EBPCs), public or private research organizations that AHRQ funds to review scientific data for USPSTF and for other AHRQ initiatives.[2] AHRQ also provides logistical, research, and technical support for the Task Force.

The Task Force describes its scope as including screening tests, counseling, and preventive medicines that are a) "offered in a primary care setting," and b) applicable to adults or children "with no signs or symptoms."[3] The Task Force has a process in place for recommendation development which includes opportunity for public comments (see Appendix A for full process). This process yields recommendations that range in grades from A to D, or an "I Statement" reflecting insufficient evidence. Both A and B grades mean that the USPSTF recommends the service.

- A grade means that the USPSTF believes there is a high certainty that the net benefit is substantial
- B grade means that there is a high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial (see Appendix B for full listing of USPSTF Grade Definitions).

The Task Force also assigns levels of certainty regarding the net benefit to the services they recommend. Services are graded as having a high, moderate or low level of

[1] Agency for Healthcare Research and Quality, "FY2012 Congressional Budget Justification" (online at http://www.ahrq.gov/about/cj2012/cjweb12.htm).
[2] AHRQ, "Evidence-Based Practice Centers" (online at www.ahrq.gov/clinic/epc/).
[3] U.S. Preventive Services Task Force, "Understanding How the U.S. Preventive Services Task Force Works" (online at www.uspreventiveservicestaskforce.org/uspstf101_slides/uspstf101.htm).

certainty as to their net benefit. (see Appendix C for a description of the levels of certainty)

Legislative History. The Task Force was convened by the Public Health Service in 1984.[4] However, it was not codified until 1999, when it appeared in the "Healthcare Research and Quality Act," as part of a section entitled "Research Supporting Primary Care and Access in Underserved Areas."[5] This codification did not link USPSTF recommendations to specific coverage requirements. In 2008, the Medicare Improvements for Patients and Providers Act, or MIPPA, gave the Secretary of Health and Human Services (the "Secretary") discretion to extend Medicare coverage to preventive services that have a USPSTF recommendation of A or B and meet other specified criteria.[6]

Affordable Care Act Changes. Most importantly, in 2010, the ACA further linked USPSTF recommendations to coverage in three key ways. First, the ACA extended the role of USPSTF recommendations in the context of Medicare. While MIPPA gave the Secretary permission to add A- and B-recommended services as covered services under Medicare, beneficiaries still faced 20 percent copayments. ACA eliminated these copayments, establishing zero out-of-pocket costs for all Medicare-covered A-and B-recommended services.[7] The decision of whether or not to include such services remains in the hands of the Secretary. In recent years, the Secretary has added a number of A- and B-recommended preventive services to Medicare coverage, including HIV Screening for At-risk Individuals and Counseling to Prevent Tobacco Use.[8]

Increased Weight and Impact of Its Recommendations. The ACA also created a new USPSTF-linked mandate for group and individual health plans, requiring all such plans, as of January 1, 2011, to cover without cost-sharing:

(1) evidence-based items or services that have in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force;

(2) immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with

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[4] U.S. Preventive Services Task Force, "Introduction" (online at www.uspreventiveservicestaskforce.org/intro.htm).

[5] P.L. 106-129, "Healthcare Research and Quality Act" (1999).

[6] 42 U.S.C. §1395x(ddd): "(1) The term 'additional preventive services' means services not described in subparagraph (A) or (C) of paragraph (3) that identify medical conditions or risk factors and that the Secretary determines are - (A) reasonable and necessary for the prevention or early detection of an illness or disability;
(B) *recommended with a grade of A or B by the United States Preventive Services Task Force*; and
(C) appropriate for individuals entitled to benefits under part A or enrolled under part B." (emphasis added)

[7] P.L. 111-148, "Patient Protection and Affordable Care Act," §4104.

[8] Centers for Medicare and Medicaid Services, "National Coverage Determination for Counseling to Prevent Tobacco Use (210.4.1)" (Aug. 25, 2010) (online at https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=342&ncdver=1&SearchType=Advanced&CoverageSelection=National&NCSelection=NCA%7cNCD%7cMCD&KeyWord=uspstf&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAACAAAAAA&); Centers for Medicare and Medicaid Services, "National Coverage Determination for Screening for the Human Immunodeficiency Virus (HIV) Infection (210.7)" (Dec. 8, 2009) (online at https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=335&ncdver=1&SearchType=Advanced&CoverageSelection=National&NCSelection=NCA%7cNCD%7cMCD&KeyWord=uspstf&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAACAAAAAA&.).

respect to the individual involved; and
(3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration.
(4) with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph.[9]
(See Appendix D for a list of USPSTF preventive services that are relevant for implementing the ACA ordered by date of recommendation.)

More Accountability and Transparency. Finally, ACA linked USPSTF recommendations to Medicaid, explicitly permitting states to add A- and B-recommended services to their Medicaid plans. While states had the ability to add services to their Medicaid plans prior to PPACA, the law created a one percent increase in FMAP, or the federal share of payment, for A- and B-recommended services if added.[10]

Along with the increased weight of USPSTF's role, ACA made several key changes to increase accountability and transparency, including requiring the Task Force to:

- Consider "clinical preventive best practice recommendations from the Agency for Healthcare Research and Quality, the National Institutes of Health, the Centers for Disease Control and Prevention, the Institute of Medicine, specialty medical associations, patient groups, and scientific societies"[11];
- Review interventions and recommendations at least once in every five-year period[12];
- "[Improve] integration with Federal Government health objectives and related target setting for health improvement"[13]; and
- Submit annual reports to Congress identifying gaps in research in preventive health and suggesting priority areas for additional research.[14]

The ACA also asserted that "[a]ll members of the Task Force convened under this subsection, and any recommendations made by such members, shall be independent and, to the extent practicable, not subject to political pressure."[15] At the same time, the ACA retained an earlier statutory provision exempting the Task Force from the requirements of the Federal Advisory Committee Act (FACA).[16] Because FACA creates strict requirements as to public comment and transparency, USPSTF's continuing FACA exemption impacts the ways in which the public can observe and comment on the Task Force's activities. This is discussed further in the sections on opportunities for input. (See Appendix E for a comparison of the original and amended codification of the USPSTF).

[9] Public Health Service Act §2713(a). The section contains an additional provision specific to mammography, discussed below.
[10] P.L. 111-148, "Patient Protection and Affordable Care Act," §4106.
[11] Public Health Service Act §915(a)(1).
[12] Public Health Service Act §915 (a)(2)(B).
[13] Public Health Service Act §915 (a)(2)(C).
[14] Public Health Service Act §915 (a)(2)(F).
[15] Public Health Service Act §915 (a)(6).
[16] Public Health Service Act §915 (a)(5).

Regulatory History. On July 19, 2010, the Departments of Health and Human Services, Labor and Treasury (the "Departments") issued an interim final regulation implementing section 2713 of the Public Health Service Act as amended by the ACA[17]. This regulation clarified the cost-sharing requirements when a recommended preventive service is provided during an office visit.

- First, if a recommended preventive service is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.
- Second, if a recommended preventive service is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.
- Finally, if a recommended preventive service is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.
- That interim final regulation provided that if a recommendation or guideline for a recommended preventive service does not specify the frequency, method, treatment, or setting for the provision of that service, the plan or issuer can use reasonable medical management techniques to determine any coverage limitations. The use of reasonable medical management techniques allows plans and issuers to adapt these recommendations and guidelines to coverage of specific items and services where cost sharing must be waived. Thus, under these regulations, a plan or issuer may rely on established techniques and the relevant evidence base to determine the frequency, method, treatment, or setting for which a recommended preventive service will be available without cost-sharing to the extent not specified in a recommendation or guideline.

The Departments then reiterated this statement on the use of reasonable medical management in a Frequently Asked Question (FAQ) released on October 8, 2010[18]. Finally, the Departments issued additional guidance on Task Force recommendations in a set of FAQs released on February 20, 2013[19]. In these FAQs, the Departments provided guidance on over-the-counter drugs, polyp removal during a colonoscopy, testing for the breast cancer susceptibility gene (BRCA), and other clarifications needed pursuant to recent USPSTF recommendations.

Statement of Problem. The intent of the provisions included in the ACA were to expand access to preventive services by eliminating cost-sharing and requiring expanded coverage. However, the recommendations issued by the USPSTF are strictly clinical and are intended to provide guidance to clinicians. Therefore, translating and implementing those recommendations into specific benefits coverage has posed difficult issues for plans and other purchasers of health care.

[17] http://www.gpo.gov/fdsys/pkg/FR-2010-07-19/pdf/2010-17242.pdf
[18] http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html#Preventive Health Services
[19] http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html

While some purchasers choose to rely on "reasonable medical management" in designing their benefits, others would prefer further clarification related to frequency, method, treatment and setting. In addition, the question has arisen of whether and how additional criteria beyond clinical evidence should be weighed in the case of each USPSTF A and B-recommended service.

Options for Process. In developing options for a process to further clarify Task Force recommendations as well as for the consideration of whether additional criteria beyond clinical evidence is appropriate, this paper contemplates several guiding principles.

- First, while the individual specialists may rotate depending on the recommendation being evaluated, the process itself should be permanent.
- Second, to minimize political opposition, the process put into place should not delay release or adoption of USPSTF recommendations.
- Third, the process should include, either through direct involvement or the ability for notice and comment, stakeholder input.
- Finally, this process should build upon a pre-existing entity or structure to the greatest extent possible. Given the sizable ramifications of USPSTF recommendation pursuant to the ACA, attempts to establish a new structure may be overwhelmed by the number of interested stakeholders.

Assuming these guiding principles, this paper outlines three different types of options: 1) publicly-funded, 2) public-private partnerships, and 3) privately-funded.

Publicly-funded.

Medicare National Coverage Determination Process. When the Secretary determines that a Task Force recommendation should be covered by the Medicare program, the Centers for Medicare and Medicaid Services issue a National Coverage Determination (NCD). The NCD augments the Task Force recommendation by further clarifying the population for whom coverage will apply based on setting, symptoms, risk, etc. The NCD also provides specifications about the covered benefit. This process could be used to clarify private coverage as well.

For example, on August 25, 2010, CMS issued a NCD on tobacco cessation counseling[20]. In order to inform the NCD, CMS issued a proposed decision and provided the public with 30 days to submit comments on this topic. CMS considered all public comments, and was particularly interested in clinical studies and other scientific information related to counseling to prevent tobacco use under review for individuals who do not yet have signs or symptoms of tobacco-related disease. They were especially interested in comments as to the types of studies needed if the evidence is determined to be premature for coverage or if the appropriate frequency interval or other coverage factors are uncertain.

[20] http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=342&ncdver=1&SearchType=Advanced&CoverageSelection=National&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&KeyWord=tobacco&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAABAAAAAAAA%3d%3d&

As part of the final NCD, CMS detailed the population for whom the counseling would be covered, outlined a coverage policy which included specifications related to frequency, and specified national non-covered indications. In each of these areas, CMS' NCD augmented the recommendation from the USPSTF. For example, the USPSTF recommendation on tobacco cessation counseling simply states that clinicians should ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products and ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling for those who smoke.

The Medicare NCD specified that CMS will cover tobacco cessation counseling for outpatient and hospitalized Medicare beneficiaries: 1) who use tobacco, regardless of whether they have signs or symptoms of tobacco-related disease; 2) who are competent and alert at the time that counseling is provided; and 3) whose counseling is furnished by a qualified physician or other Medicare-recognized practitioner.

The USPSTF recommendation did not address frequency. The Medicare NCD augmented the recommendation by specifying that similar to existing tobacco cessation counseling for symptomatic individuals, CMS will allow two individual tobacco cessation counseling attempts per 12-month period. Each attempt may include a maximum of four intermediate or intensive sessions, with a total benefit covering up to eight sessions per 12-month period per Medicare beneficiary who uses tobacco. The practitioner and patient have the flexibility to choose between intermediate (more than three minutes but less than ten minutes), or intensive (more than ten minutes) cessation counseling sessions for each attempt.

Finally, the Medicare NCD stated that inpatient hospital stays with the principal diagnosis of tobacco use disorder are not reasonable and necessary for the effective delivery of tobacco cessation counseling services. Therefore, Medicare excludes coverage of tobacco cessation services if tobacco cessation is the primary reason for the patient's hospital stay.

Pros

- It is an already established system run by Medicare staff with expertise in coverage policy.
- It would be binding on the Department in terms of enforcement.
- It is already funded through CMS' appropriations.

Cons

- While it allows for comments by stakeholders, it does not allow for direct involvement in the policy development process.
- It may require legislation to allow NCDs to further clarify Task Force recommendations.
- Because any Federal guidance related to Section 2713 of the ACA must be promulgated from the Departments, the process may not be timely enough.
- CMS does not directly experience the need to moderate costs, or balance costs and benefits, so the problem of affordability that employers struggle with may not be addressed.

HHS Subregulatory Guidance. The only clarifications of the Task Force recommendations issued by the Department thus far have come in the form of subregulatory guidance, specifically as FAQs. To date, the FAQs have provided necessary but not sufficient clarifications of the recommendations and the regulated community has relied on "reasonable medical management", as specifically allowed by the Departments, to assess questions of frequency, method, setting, etc. The Departments could be mandated, either through legislation or Executive Order, to solicit areas which require clarification from the regulated community, issue draft subregulatory guidance and solicit comment prior to the finalization of that guidance.

Pros

- It is an already established system informed by staff with expertise in coverage policy.
- It would be binding on the Department in terms of enforcement.
- It is already funded through CMS' appropriations.

Cons

- While it allows for comments by stakeholders, it does not allow for direct involvement in the policy development process.
- Because any Federal guidance related to Section 2713 of the ACA must be promulgated from the Departments, the process may not be timely enough.
- HHS does not directly experience the need to moderate costs, or balance costs and benefits, so the problem of affordability that employers struggle with may not be addressed.

Secretary's Coverage Policy Committee. The Secretary and the CMS Administrator have a number of advisory panels, counsels and boards which have been created over time to make recommendations on different matters within the Department's purview. For example, the Advisory Panel on Outreach and Education (APOE) advises the Secretary and the CMS Administrator on optimal strategies for developing and implementing education and outreach programs for individuals enrolled in, or eligible for, Medicare, Medicaid and the Children's Health Insurance Program (CHIP).[21]

Another example is the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) which was established to provide independent guidance and expert advice to CMS on specific clinical topics. The MEDCAC reviews and evaluates medical literature, technology assessments, and examines data and information on the effectiveness and appropriateness of medical items and services that are covered under Medicare, or that may be eligible for coverage under Medicare. The MEDCAC judges the strength of the available evidence and makes recommendations to CMS based on that evidence. The Committee works from an agenda provided by the Designated Federal Official (DFO) that lists specific issues, and will develop technical advice in order to assist CMS in determining reasonable and necessary uses of medical services and

[21] http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/APOE.html

technology. The Committee may be asked to develop recommendations about specific issues of Medicare coverage, and/or to review and comment upon proposed or existing Medicare coverage policies. CMS may also ask the Committee to comment on pertinent aspects of proposals being considered and/or other policies.[22]
To staff the MEDCAC, the Secretary selects up to 100 experts in clinical and administrative medicine, biologic and physical sciences, public health administration, patient advocacy, health care data and information management and analysis, health care economics, and medical ethics. This pool of 100 appointed members consists of 94 voting members of whom six are designated patient advocates, and six are nonvoting representatives of industry interested. No more than 15 members with knowledge specific to the topic in question are selected to serve on the panel for each MEDCAC meeting and non-MEDCAC members who have relevant expertise may be invited to provide additional input or make formal presentations to the MEDCAC for a particular meeting. The panel meets in a public forum approximately 4-8 times a year to review medical evidence for the topic under deliberation, listen to public testimony, and provide advice about the quality of the evidence. [23]

As membership terms expire, the Department seeks nominations in the Federal Register for both voting and nonvoting members to serve on the MEDCAC. Nominees are selected based upon their individual qualifications and not as representatives of professional associations or societies.

While the MEDCAC itself is not chartered for the purpose of reviewing and augmenting the USPSTF recommendations, it provides a potential process for establishing, chartering and nominating a committee to perform this function. As with MEDCAC, this committee could be governed by provisions of the FACA and would provide recommendations directly to the Secretary who could incorporate those recommendations into subregulatory or regulatory guidance. The charter could require that the members of the committee have experience both in reviewing medical literature, translating that literature into coverage, making and implementing coverage decisions, and related expertise, such as insurance, actuarial, and health care strategy.

Pros

- This builds on an existing, accepted and workable model that is familiar to the Department.
- Stakeholders would have input through the nominations process and could work to ensure the original charter required the involvement of coverage experts and purchasers.
- A Coverage Policy Committee that is FACA compliant can be chartered by the Secretary without legislative authority.
- It does not change or delay the Task Force process for developing recommendations and, therefore, should be politically palatable.

Cons

- Because any Federal guidance related to Section 2713 of the ACA must be promulgated from the Departments, the process may not be timely enough.

[22] http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/medcaccharter.pdf
[23] http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/MEDCAC.html

- The recommendations made by the committee will not be binding on the Secretary.
- The Committee may not feel sufficient concern about costs since they will have no direct connection with the total costs of the package of benefits.

VBID. Section 2713(c) of the ACA allows the Secretary to develop guidelines to permit a group health plan and a health insurance issuer offering group or individual health insurance coverage to utilize value-based insurance designs (VBID). This provision could provide purchasers more flexibility to design the benefits mandated under Section 2713 of the ACA by allowing the use of non-clinical criteria to assess the application of preventive benefits and to specify frequency, method, setting, etc. In fact, the Department has implicitly permitted cost considerations in the context of VBID already.

In a FAQ released by the Department, they clarified that a plan design that does not impose a copayment for colorectal cancer preventive services when performed in an in-network ambulatory surgery center but does require a copayment when the same preventive service is provided at an in-network outpatient hospital setting is permissible. Specifically, the FAQ stated that "regulations the Departments issued to implement the preventive health benefits in the ACA recognized the important role that VBID can play in promoting the use of appropriate, high value preventive services and providers. Plans may use reasonable medical management techniques to steer patients towards a particular high-value setting such as an ambulatory care setting for providing preventive care services, provided the plan accommodates any individuals for whom it would be medically inappropriate to have the preventive service provided in the ambulatory setting (as determined by the attending provider) by having a mechanism for waiving the otherwise applicable copayment for the preventive services provided in a hospital." The Departments also stated that "on or about the date of issuance of these FAQs, the Departments will be issuing a Request for Information on ways the Departments can encourage VBID in the context of preventive care services. However, regulations implementing this provision have never been promulgated. The Secretary could be mandated, either through legislation or Executive Order, to promulgate regulations implementing the value-based insurance design provision of the ACA.

Pro

- The regulations could provide purchasers the ability to augment the Task Force recommendations without the potential for further conflicting guidance.

Cons

- It may not be a timely solution given that the ACA is permissive and, therefore, an additional requirement must be placed on the Secretary to issue regulations and then regulations must be promulgated.
- There is always the possibility, given the lack of predictability of the regulatory process, that the regulations will not allow as much flexibility for purchasers as they may want.

Public-Private Partnerships

USPSTF Public Comment Period and Process. USPSTF is not subject to the requirements of the FACA which mandates public notice in advance of meetings, public meetings (with some exceptions), public availability of meetings minutes, and other requirements related to transparency.[24] However, while not statutorily required, USPSTF has developed mechanisms for input into the recommendation development process. Some of these are available to the general public, while others involve input from specific partner entities. Specifically, the public may comment during three specific stages of recommendation development.

- First, during the development of a research plan (see Table 1, step 1). In late 2011, the Task Force began posting draft research plans online for four weeks for public comment.
- Second, the public may comment on the draft research report (see Table 1, step 2). USPSTF has announced that in the future, evidence reviews developed by the Evidence-based Practice Centers will be posted for public comment.
- Third, the public may comment on the draft recommendation statement (see Table 1, steps 4-6). Recommendation statements drafted by the full Task Force are posted online for four weeks for public comment. In addition to commenting on these documents, anyone may nominate a topic for USPSTF consideration.[25]

Finally, anyone may request reconsideration of an existing recommendation. Reconsiderations may be requested based on new evidence, a change in the public health burden, or the availability of new screening tests.[26] For some topics, the Task Force also holds "topic groups" for stakeholders. These briefings or webinars, held toward the beginning of the recommendation development process when a draft research plan is developed, allow potential stakeholders – usually national organizations – to hear how the research plan was developed, and express any concerns or questions.[27]

Stakeholders could advocate for extended or more inclusive comment processes or for the Task Force to address comments specifically in a public manner. Stakeholders could advocate to have the Secretary ask for input from the AHRQ, CBO, and CMS about the costs of what is being considered at the same time as the evidence reviews and recommendations. In addition, those interested in the Task Force or specific recommendations may consider a number of informal avenues for providing input. For example, there does not appear to be a prohibition against meeting with individual

[24] Federal Advisory Committee Act, 5 U.S.C. *App. 2,* **§ 10.**
[25] U.S. Preventive Services Task Force, "Nominate a Recommendation Statement Topic" (online at www.uspreventiveservicestaskforce.org/tftopicnom.htm).
[26] U.S. Preventive Services Task Force, "Topic Reconsideration Form," (online at www.uspreventiveservicestaskforce.org/uspstf_TopicRcnsdr/).
[27] Conversation with AHRQ staff, January 26, 2012.

members of the USPSTF. For each review topic, three or four Task Force members are appointed as "topic leads." These leads take primary responsibility for various stages of the recommendation development process. Interested parties may wish to identify the topic leads for the relevant issue and meet or communicate with them to request that key data and concerns are addressed.

USPSTF Partner Organizations. The Task Force is assisted by a number of "Partner Organizations", federal and non-federal, that can attend all Task Force meetings and that provide comment on draft Task Force documents. The federal partners are the Centers for Disease Control and Prevention (CDC), Centers for Medicare and Medicaid Services (CMS), Department of Defense (DOD) Military Health System, Department of Veterans Affairs (VA) Center for Health Promotion and Disease Prevention, Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), and U.S. Food and Drug Administration (FDA).[28]

Non-federal partners are the American Academy of Family Physicians (AAFP), American Academy of Nurse Practitioners (AANP), American Academy of Pediatrics (AAP), American Academy of Physician Assistants (AAPA), American College of Obstetricians and Gynecologists (ACOG), American College of Physicians (ACP), American College of Preventive Medicine (ACPM), American Osteopathic Association (AOA), National Association of Pediatric Nurse Practitioners (NAPNAP), America's Health Insurance Plans (AHIP), AARP, and the National Committee for Quality Assurance (NCQA).[29]

Because of the Task Force's exemption from FACA, meetings are not required to be open to the public. However, partner organizations are invited to attend each meeting of the Task Force, both to observe and to provide expertise.[30] In addition, they review draft Task Force documents, coordinate review by their members, and test draft educational materials.[31]

Interested parties could approach these partners separately or advocate that the Partner Organizations be given the task of deliberating on the appropriate non-clinical criteria which must be weighed for each recommendation and any appropriate specification which should be included for translation of medical literature into coverage and practice. The Partner Organizations could then make recommendations to the Task Force which must be considered as part of its deliberations. As part of this option, the recommendation would include the addition of a representative for self-funded plans to the group of non-federal partners. While fully-funded plans are represented by AHIP, self-funded plans are not represented and would need to be added in order to ensure the recommendations made by the partners are balanced and representative of each

[28] U.S. Preventive Services Task Force, USPSTF Procedure Manual, "Section 1: Section 1: Overview of U.S. Preventive Services Task Force Structure and Processes," (online at www.uspreventiveservicestaskforce.org/uspstf08/methods/procmanual1.htm).
[29] U.S. Preventive Services Task Force, "Role of Partners" (online at www.uspreventiveservicestaskforce.org/partners.htm).
[30] U.S. Preventive Services Task Force, USPSTF Procedure Manual, "Section 1: Section 1: Overview of U.S. Preventive Services Task Force Structure and Processes," (online at www.uspreventiveservicestaskforce.org/uspstf08/methods/procmanual1.htm).
[31] Conversation with AHRQ staff, January 26, 2012.

stakeholder community. There should also be an official role for coverage and benefit design experts, OPM, and the American Academy of Actuaries.

See Appendix F for other options that were considered and rejected.

Appendix A

Table 1: USPSTF Recommendation Development[32]

1. Research Plan Development: Evidence-based Practice Center (EPC) and Task Force topic workgroup, with input from AHRQ medical officers, create a research plan that guides the recommendation process.
2. Evidence Review: EPC independently gathers and reviews the available published evidence. Evidence review critiqued by external national subject matter experts.
3. Draft Recommendation Development: USPSTF topic workgroup discusses the evidence and drafts a preliminary recommendation.
4. Full Task Force Review: Evidence report and draft recommendation statement are presented to the Task Force. All members discuss draft recommendation statement. Topic workgroup then drafts the full recommendation language, including clinical considerations and discussion.
5. Public Comment Opportunity: The evidence report is finalized and published. The draft recommendation is posted on the USPSTF Web Site for public comment.
6. Task Force Review of Public Comments: Public and partner comments are reviewed by Task Force and addressed as appropriate.
7. Task Force Vote: Task Force votes to ratify the final recommendation statement.
8. Final Recommendation Published: Most final recommendations are published in either *Annals of Internal Medicine*, *Pediatrics*, or *Annals of Family Medicine*. All recommendations and supporting evidence reports are published on the Task Force Web site.

[32] U.S. Preventive Services Task Force, "Understanding How the U.S. Preventive Services Task Force Works" (online at www.uspreventiveservicestaskforce.org/uspstf101_slides/uspstf101.htm).

Appendix B

Table 2: USPSTF Grade Definitions[33]

A: The USPSTF recommends the service. There is high certainty that the net benefit is substantial.
B: The USPSTF recommends the service. There is high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial.
C: *Note: The following statement is undergoing revision.* Clinicians may provide this service to selected patients depending on individual circumstances. However, for most individuals without signs or symptoms there is likely to be only a small benefit from this service.
D: The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.
I Statement: The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits & harms of the service.

[33] U.S. Preventive Services Task Force, "Understanding How the U.S. Preventive Services Task Force Works" (online at www.uspreventiveservicestaskforce.org/uspstf101_slides/uspstf101.htm).

Appendix C
USPSTF Levels of Certainty Regarding Net Benefit

Level of Certainty*	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: • The number, size, or quality of individual studies • Inconsistency of findings across individual studies • Limited generalizability of findings to routine primary care practice • Lack of coherence in the chain of evidence As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: • The limited number or size of studies • Important flaws in study design or methods • Inconsistency of findings across individual studies • Gaps in the chain of evidence • Findings not generalizable to routine primary care practice • A lack of information on important health outcomes More information may allow an estimation of effects on health outcomes.

*The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Appendix D

USPSTF A and B Recommendations by Date

The following is a list of preventive services that have a rating of A or B from the U.S. Preventive Services Task Force that are relevant for implementing the Affordable Care Act. The preventive services are listed by date of release of the current recommendation.

Release Date of Current Recommendation	Topic	Description	Grade
June 2013	Hepatitis C virus infection screening: adults	The USPSTF recommends screening for hepatitis C virus (HCV) infection in persons at high risk for infection. The USPSTF also recommends offering one-time screening for HCV infection to adults born between 1945 and 1965.	B
May 2013*	Alcohol misuse: screening and counseling	The USPSTF recommends that clinicians screen adults age 18 years or older for alcohol misuse and provide persons engaged in risky or hazardous drinking with brief behavioral counseling interventions to reduce alcohol misuse.	B
April 2013*	HIV screening: nonpregnant adolescents and adults	The USPSTF recommends that clinicians screen for HIV infection in adolescents and adults ages 15 to 65 years. Younger adolescents and older adults who are at increased risk should also be screened.	A
April 2013*	HIV screening: pregnant women	The USPSTF recommends that clinicians screen all pregnant women for HIV, including those who present in labor who are untested and whose HIV status is unknown.	A
January 2013	Intimate partner violence screening: women of childbearing age	The USPSTF recommends that clinicians screen women of childbearing age for intimate partner violence, such as domestic violence, and provide or refer women who screen positive to intervention services. This recommendation applies to women who do not have signs or symptoms of abuse.	B
June 2012*	Obesity screening and counseling: adults	The USPSTF recommends screening all adults for obesity. Clinicians should offer or refer patients with a body mass index of 30 kg/m^2 or higher to intensive, multicomponent behavioral interventions.	B
May 2012	Falls prevention in older adults: exercise or physical therapy	The USPSTF recommends exercise or physical therapy to prevent falls in community-dwelling adults age 65 years and older who are at increased risk for falls.	B
May 2012	Falls prevention in older adults: vitamin D	The USPSTF recommends vitamin D supplementation to prevent falls in community-dwelling adults age 65 years and older who are at increased risk for falls.	B
May 2012	Skin cancer behavioral counseling	The USPSTF recommends counseling children, adolescents, and young adults ages 10 to 24 years who have fair skin about minimizing their exposure to ultraviolet radiation to reduce risk for skin cancer.	B

March 2012*	Cervical cancer screening	The USPSTF recommends screening for cervical cancer in women ages 21 to 65 years with cytology (Pap smear) every 3 years or, for women ages 30 to 65 years who want to lengthen the screening interval, screening with a combination of cytology and human papillomavirus (HPV) testing every 5 years.	A
January 2012*	Osteoporosis screening: women	The USPSTF recommends screening for osteoporosis in women age 65 years and older and in younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has no additional risk factors.	B
July 2011*	Gonorrhea prophylactic medication: newborns	The USPSTF recommends prophylactic ocular topical medication for all newborns for the prevention of gonococcal ophthalmia neonatorum.	A
January 2011*	Visual acuity screening in children	The USPSTF recommends vision screening for all children at least once between the ages of 3 and 5 years, to detect the presence of amblyopia or its risk factors.	B
January 2010	Obesity screening and counseling: children	The USPSTF recommends that clinicians screen children age 6 years and older for obesity and offer them or refer them to comprehensive, intensive behavioral interventions to promote improvement in weight status.	B
December 2009	Depression screening: adults	The USPSTF recommends screening adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up.	B
June 2009	Hepatitis B screening: pregnant women	The USPSTF strongly recommends screening for hepatitis B virus infection in pregnant women at their first prenatal visit.	A
May 2009	Folic acid supplementation	The USPSTF recommends that all women planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg (400 to 800 µg) of folic acid.	A
May 2009	Syphilis screening: pregnant women	The USPSTF recommends that clinicians screen all pregnant women for syphilis infection.	A
April 2009	Tobacco use counseling and interventions: nonpregnant adults	The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products.	A
April 2009	Tobacco use counseling: pregnant women	The USPSTF recommends that clinicians ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling to those who smoke.	A
March 2009	Aspirin to prevent cardiovascular disease: men	The USPSTF recommends the use of aspirin for men ages 45 to 79 years when the potential benefit due to a reduction in myocardial infarctions outweighs the potential harm due to an increase in gastrointestinal hemorrhage.	A
March 2009	Aspirin to prevent	The USPSTF recommends the use of aspirin for	A

	cardiovascular disease: women	women ages 55 to 79 years when the potential benefit of a reduction in ischemic strokes outweighs the potential harm of an increase in gastrointestinal hemorrhage.	
March 2009	Depression screening: adolescents	The USPSTF recommends screening adolescents (ages 12 to 18 years) for major depressive disorder when systems are in place to ensure accurate diagnosis, psychotherapy (cognitive-behavioral or interpersonal), and follow-up.	B
October 2008	Breastfeeding counseling	The USPSTF recommends interventions during pregnancy and after birth to promote and support breastfeeding.	B
October 2008	Colorectal cancer screening	The USPSTF recommends screening for colorectal cancer using fecal occult blood testing, sigmoidoscopy, or colonoscopy in adults beginning at age 50 years and continuing until age 75 years. The risks and benefits of these screening methods vary.	A
October 2008	Sexually transmitted infections counseling	The USPSTF recommends high-intensity behavioral counseling to prevent sexually transmitted infections (STIs) in all sexually active adolescents and for adults at increased risk for STIs.	B
July 2008	Bacteriuria screening: pregnant women	The USPSTF recommends screening for asymptomatic bacteriuria with urine culture in pregnant women at 12 to 16 weeks' gestation or at the first prenatal visit, if later.	A
July 2008	Hearing loss screening: newborns	The USPSTF recommends screening for hearing loss in all newborn infants.	B
June 2008	Cholesterol abnormalities screening: men 35 and older	The USPSTF strongly recommends screening men age 35 years and older for lipid disorders.	A
June 2008	Cholesterol abnormalities screening: men younger than 35	The USPSTF recommends screening men ages 20 to 35 years for lipid disorders if they are at increased risk for coronary heart disease.	B
June 2008	Cholesterol abnormalities screening: women 45 and older	The USPSTF strongly recommends screening women age 45 years and older for lipid disorders if they are at increased risk for coronary heart disease.	A
June 2008	Cholesterol abnormalities screening: women younger than 45	The USPSTF recommends screening women ages 20 to 45 years for lipid disorders if they are at increased risk for coronary heart disease.	B
June 2008	Diabetes screening	The USPSTF recommends screening for type 2 diabetes in asymptomatic adults with sustained blood pressure (either treated or untreated) greater than 135/80 mm Hg.	B
March 2008	Hypothyrodism screening: newborns	The USPSTF recommends screening for congenital hypothyroidism in newborns.	A

March 2008	Phenylketonuria screening: newborns	The USPSTF recommends screening for phenylketonuria in newborns.	A
December 2007	Blood pressure screening in adults	The USPSTF recommends screening for high blood pressure in adults age 18 years and older.	A
September 2007	Hemoglobinopathies screening: newborns	The USPSTF recommends screening for sickle cell disease in newborns.	A
June 2007	Chlamydial infection screening: nonpregnant women	The USPSTF recommends screening for chlamydial infection in all sexually active nonpregnant young women age 24 years and younger and for older nonpregnant women who are at increased risk.	A
June 2007	Chlamydial infection screening: pregnant women	The USPSTF recommends screening for chlamydial infection in all pregnant women age 24 years and younger and for older pregnant women who are at increased risk.	B
May 2006	Anemia screening: pregnant women	The USPSTF recommends routine screening for iron deficiency anemia in asymptomatic pregnant women.	B
May 2006	Iron supplementation in children	The USPSTF recommends routine iron supplementation for asymptomatic children ages 6 to 12 months who are at increased risk for iron deficiency anemia.	B
September 2005	BRCA screening, counseling about	The USPSTF recommends that women whose family history is associated with an increased risk for deleterious mutations in *BRCA1* or *BRCA2* genes be referred for genetic counseling and evaluation for BRCA testing.	B
May 2005	Gonorrhea screening: women	The USPSTF recommends that clinicians screen all sexually active women, including those who are pregnant, for gonorrhea infection if they are at increased risk for infection (that is, if they are young or have other individual or population risk factors).	B
February 2005	Abdominal aortic aneurysm screening: men	The USPSTF recommends one-time screening for abdominal aortic aneurysm by ultrasonography in men ages 65 to 75 years who have ever smoked.	B
July 2004	Syphilis screening: nonpregnant persons	The USPSTF strongly recommends that clinicians screen persons at increased risk for syphilis infection.	A
April 2004	Dental caries prevention: preschool children	The USPSTF recommends that primary care clinicians prescribe oral fluoride supplementation at currently recommended doses to preschool children older than age 6 months whose primary water source is deficient in fluoride.	B
February 2004	Rh incompatibility screening: first pregnancy visit	The USPSTF strongly recommends Rh (D) blood typing and antibody testing for all pregnant women during their first visit for pregnancy-related care.	A
February 2004	Rh incompatibility screening: 24–28 weeks' gestation	The USPSTF recommends repeated Rh (D) antibody testing for all unsensitized Rh (D)-negative women at 24 to 28 weeks' gestation, unless the biological father is known to be Rh (D)-	B

		negative.	
January 2003	Healthy diet counseling	The USPSTF recommends intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. Intensive counseling can be delivered by primary care clinicians or by referral to other specialists, such as nutritionists or dietitians.	B
September 2002†	Breast cancer screening	The USPSTF recommends screening mammography for women, with or without clinical breast examination, every 1 to 2 years for women age 40 years and older.	B
July 2002	Breast cancer preventive medication	The USPSTF recommends that clinicians discuss chemoprevention with women at high risk for breast cancer and at low risk for adverse effects of chemoprevention. Clinicians should inform patients of the potential benefits and harms of chemoprevention.	B

†The Department of Health and Human Services, in implementing the Affordable Care Act under the standard it sets out in revised Section 2713(a)(5) of the Public Health Service Act, utilizes the 2002 recommendation on breast cancer screening of the U.S. Preventive Services Task Force. To see the USPSTF 2009 recommendation on breast cancer screening, go to http://www.uspreventiveservicestaskforce.org/uspstf/uspsbrca.htm.
* Previous recommendation was an "A" or "B."

Current as of June 2013

Appendix E

Table 3: Comparison of Original and Amended Codification of the USPSTF:

Original codification in the Healthcare Research and Quality Act (1999)	**Patient Protection and Affordable Care Act (2010)**
``(1) Establishment and purpose.--The Director may periodically convene a Preventive Services Task Force to be composed of individuals with appropriate expertise. Such a task force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community, and updating previous clinical preventive recommendations.	‘‘(1) ESTABLISHMENT AND PURPOSE.—The Director shall convene an independent Preventive Services Task Force (referred to in this subsection as the ‘Task Force’) to be composed of individuals with appropriate expertise. Such Task Force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community, and updating previous clinical preventive recommendations, to be published in the Guide to Clinical Preventive Services (referred to in this section as the ‘Guide’), for individuals and organizations delivering clinical services, including primary care professionals, health care systems, professional societies, employers, community organizations, non-profit organizations, Congress and other policy-makers, governmental public health agencies, health care quality organizations, and organizations developing national health objectives. Such recommendations shall consider clinical preventive best practice recommendations from the Agency for Healthcare Research and Quality, the National Institutes of Health, the Centers for Disease Control and Prevention, the Institute of Medicine, specialty medical associations, patient groups, and scientific societies.
	‘‘(2) DUTIES.—The duties of the Task Force shall include— ‘‘(A) the development of additional topic areas for new recommendations and interventions related to those topic areas, including those related to specific sub-populations and age groups; ‘‘(B) at least once during every 5-year period, review interventions and update

	recommendations related to existing topic areas, including new or improved techniques to assess the health effects of interventions; ‘‘(C) improved integration with Federal Government health objectives and related target setting for health improvement; ‘‘(D) the enhanced dissemination of recommendations; ‘‘(E) the provision of technical assistance to those health care professionals, agencies and organizations that request help in implementing the Guide recommendations; and ‘‘(F) the submission of yearly reports to Congress and related agencies identifying gaps in research, such as preventive services that receive an insufficient evidence statement, and recommending priority areas that deserve further examination, including areas related to populations and age groups not adequately addressed by current recommendations.
``(2) Role of agency.--The Agency [AHRQ] shall provide ongoing administrative, research, and technical support for the operations of the Preventive Services Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force.	‘‘(3) ROLE OF AGENCY.—The Agency [AHRQ] shall provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of the Guide’s recommendations.
	‘‘(4) COORDINATION WITH COMMUNITY PREVENTIVE SERVICES TASK FORCE.—The Task Force shall take appropriate steps to coordinate its work with the Community Preventive Services Task Force and the Advisory Committee on Immunization Practices, including the examination of how each task force’s recommendations interact at the nexus of clinic and community.
``(3) Operation.--In carrying out its	‘‘(5) OPERATION.—Operation. In

responsibilities under paragraph (1), the Task Force is not subject to the provisions of Appendix 2 of title 5, United States Code.[34]	carrying out the duties under paragraph (2), the Task Force is not subject to the provisions of Appendix 2 of title 5, United States Code.
	‘‘(6) INDEPENDENCE.—All members of the Task Force convened under this subsection, and any recommendations made by such members, shall be independent and, to the extent practicable, not subject to political pressure.
	‘‘(7) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out the activities of the Task Force.’’.

[34] P.L. 106-129, “Healthcare Research and Quality Act of 1999”, Section 915(a).

Appendix F

Other Options Considered

USPSTF New Appointees. The USPSTF appoints each of its members for four year staggered terms. There will be four new members appointed this year. Stakeholders could advocate that those new members be individuals with not only the ability to read and digest medical literature but with a demonstrated ability to translate medical research and literature into practice.

Pro of any approach which attempts to change or amend the current Task Force

- It forces the members of the Task Force itself to acknowledge the weight of its recommendations and take ownership of the coverage implications.

Cons

- Many would argue it muddles the Task Force's mission; that they have no expertise in coverage and should not attempt to develop that expertise without the input of stakeholders and there is no way to compel the Task Force to act.
- Stakeholders could advocate for a change in their deliberations but the Task Force itself makes the final decision about which changes they will make to their process.

Institute of Medicine. The Institute of Medicine (IOM) is an independent, nonprofit organization that works outside of government to provide unbiased and authoritative advice to decision makers and the public. The Administration has relied upon the IOM to make recommendations related to two key provisions of the ACA - the women's preventive services as well as the essential health benefits provision.

In addition to the studies conducted by the IOM, they also form standing committees composed of experts in their field which guide the IOM's work on a relatively narrow subject area but do not issue reports. Standing committees may be established for unspecified terms, anticipating a sponsors' need for continuing advice. The IOM could create a standing committee to apply non-clinical criteria to the Task Force recommendations and clarify the coverage parameters. This standing committee could be mandated by Congress or requested by a federal agency or an independent organization.

Pro

- IOM is independent and flexible enough to staff a standing committee with individuals with the correct expertise to address different recommendations.

Con

- The process requires funding from the requesting entity or from the Congressional appropriations process which may be difficult to identify and there are some in Congress who view the IOM as too liberal and may criticism an increased role for them in this process.

American Academy of Pediatrics and Health Resources and Services Administration Partnership on Bright Futures. The ACA requires coverage, "with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA)". These guidelines are informed by Bright Futures. The Bright Futures initiative was launched in 1990 under the leadership of the Maternal and Child Health Bureau (MCHB) of HRSA and is run in collaboration with the American Academy of Pediatrics (AAP). The goal of Bright Futures is to improve the quality of health services for children through health promotion and disease prevention.

Bright Futures, in conjunction with the AAP, releases "Recommendations for Preventive Pediatric Health Care" which is updated periodically. To help practitioners and purchasers translate these recommendations into coverage, Bright Futures also releases a "Coding for Pediatric Preventive Care Manual". This coding resource is organized for easy access and accurate reference and contains comprehensive listings of all the current CPT and ICD-9-CM Codes that are commonly reported by pediatric health care practitioners in providing preventive care services[35]. Bright Futures also releases the "Performing Preventive Services: A Bright Futures Handbook". This handbook is designed to provide guidance about the most effective and efficient ways to deliver preventive services. It's described as "Ideal for pediatric health professionals in practice, and as a teaching tool for medical students, residents, public health workers and all health professionals who provide well child care to infants, children and adolescents and their families". Finally, they release a "Bright Futures Tool and Resource Kit". This tool and resource kit provides materials for health supervision care from infancy through adolescence. It is designed to accompany and support "Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents, Third Edition".

While Bright Futures is obviously specific to pediatric care and, therefore, not the appropriate venue for consideration and augmentation of the Task Force recommendations, it does provide a good example of the type of support materials and resources the Task Force could be requested or mandated to supply for their recommendations. In addition, Bright Futures also has an exemplary and established process that includes input from stakeholders to develop their support resources.

Pro

- It does not change or delay the Task Force process for developing recommendations and, therefore, should be politically palatable and it involves direct stakeholder input.

Con

- While it could involve direct stakeholder input, not all stakeholders can be represented and those not involved will not have the opportunity for notice and comment.

Privately Funded

[35] http://brightfutures.aap.org/clinical_practice.html

Aetna Clinical Policy Council. Aetna has a clinical policy council that issues Clinical Policy Bulletins (CPBs) which are publicly available. Aetna CPBs are detailed and technical documents that explain how Aetna makes coverage decisions for members under their health benefit plans. They spell out what medical, dental, pharmacy and behavioral health technologies and services may or may not be covered. CPBs are based on evidence from objective, credible sources such as scientific literature, technology reviews, consensus statements, expert opinions, guidelines from national professional health care organization and public health agencies.

Medical CPBs state Aetna's policies on the experimental and investigational status and medical necessity of medical technologies and services. Dental CPBs state their policies on various diagnostic, preventive, endodontic, periodontic, implant, oral surgery and orthodontic technologies and services. Pharmacy CPBs state our policies on selected prescription drugs, primarily drugs on the Formulary Exclusion list, and drugs requiring Precertification or Step-Therapy[36]. In developing CPBs, Aetna analyzes the costs and benefits of new technologies and services compared to current treatments and deliberates on the clinical utility versus financial analysis. Using this analysis, the CPBs also detail medical management tools that should be used for certain treatments such as pre-certification or pre-authorization. Current CPBs exist for a number of preventive services such as colorectal cancer screening, cervical cancer screening and diagnosis, mammography, and bone mass measurement.

Purchasers could choose to follow the Aetna CPBs and use the parameters specified in the CPBs to design their own benefits.

Pro

- It is a privately funded, established process which is informed by, medical, economic and coverage experts.

Cons

- It would not allow for stakeholder input,
- It may not specifically address each Task Force recommendation, and
- It is not binding on the Department. In essence, it would provide purchasers with an intellectual safe harbor rather than a real safe harbor.

[36] http://www.aetna.com/healthcare-professionals/policies-guidelines/clinical_policy_bulletins.html