



Medicare Coverage of Clinical Preventive Services

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March 18, 2010

Congressional Research Service

7-....

www.crs.gov

R40978

Summary

Congress established the Medicare program in 1965 in response to concerns that many seniors did not have health insurance, or had insurance that only covered hospital inpatient services. Historically, Medicare covered only diagnostic and treatment services, not preventive services provided in the absence of illness. Generally, adding coverage of a preventive service required statutory authority. Since 1980, Congress has established Medicare coverage for several preventive services in law. Recently, Congress gave the Secretary of HHS limited authority to cover new Medicare preventive services administratively.

While many view preventive services as a means to improve the quality of health care by preventing illness, disability, and death, some have also touted prevention as a means to contain health care costs. However, whether expanding coverage or utilization of preventive services would actually save money for Medicare is a matter of debate. While these screenings may be effective in preventing premature death or other unwanted outcomes in some beneficiaries, their broad use may incur a net cost for the Medicare program, rather than savings.

Efforts have also been made to determine whether specific preventive services are effective, and whether their use would be likely to benefit the patient without posing potential risks from the procedure itself. Congress has in the past sought the advice of expert panels to make these assessments. However, none of these panels is explicitly charged with evaluating preventive services for the purposes of Medicare coverage. For example, current Medicare coverage of preventive services does not always comport with evidence-based recommendations of a prominent expert panel, the U.S. Preventive Services Task Force (USPSTF). A recent USPSTF recommendation regarding screening mammography has refocused congressional attention on the appropriate role of advisory panels with respect to Medicare coverage decisions.

In November 2009, the House passed the Affordable Health Care for America Act (H.R. 3962). In December 2009, the Senate passed the Patient Protection and Affordable Care Act (an amendment to H.R. 3590). Each bill would, in general, expand Medicare coverage of preventive services, and reduce or eliminate most cost-sharing for these services. The Congressional Budget Office (CBO) has scored most of these proposals as incurring a net cost for Medicare. The House is preparing to vote on Senate-passed H.R. 3590 and on an accompanying reconciliation bill (H.R. 4872) that would change several controversial elements in the Senate-passed bill and otherwise amend it so that its budgetary impact meets the reconciliation instructions in last year's budget resolution. If the House approves H.R. 3590, it will be sent to the President to be signed into law. The reconciliation measure, if approved by the House, would then be taken up by the Senate.

This report first discusses the legislative and administrative history of Medicare coverage of preventive services. Then it discusses several advisory panels that have evaluated the effectiveness of preventive services, Medicare coverage of these services, or utilization of these services. Next, it discusses whether or not the use of preventive services would be cost-saving or cost-effective for Medicare, and whether utilization of preventive services can be improved. The report then presents relevant proposals in pending health reform legislation. Finally, the **Appendix** compares current Medicare coverage of preventive services with current USPSTF recommendations. This report will be updated to reflect legislative and other activity.

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Introduction

The role of prevention in improving the quality of health care by preventing illness, disability, and death through expanded coverage or use of preventive services is a key topic of discussion among those seeking to reform the nation's health care delivery system. Many argue that preventive services have the potential to greatly improve patients' health. They cite, among other things, the burdens of disease and premature death that result from tobacco use, poor diet, and other unhealthy behaviors. Preventive services that improve health outcomes are seen as a means to improve the quality of care provided by the nation's health care system.

Chronic diseases place a growing health burden on older Americans, and an increasing cost burden on the Medicare program.¹ According to the Congressional Budget Office (CBO), "without any changes in federal law, total spending on health care will rise from 16 percent of GDP in 2007 to 25 percent in 2025 and close to 50 percent in 2082; net federal spending on Medicare and Medicaid will rise from 4 percent of GDP to almost 20 percent over the same period. Many of the other factors that will play a role in determining future fiscal conditions over the long term pale by comparison with the challenges of containing growth in the cost of federal health insurance programs."²

Some stakeholders have touted prevention as a means to contain health care costs.³ Whether expanding coverage or utilization of preventive services would actually save money for Medicare is, however, a matter of continuing debate.

What Are Clinical Preventive Services?

Clinical preventive services have been defined as "interventions comprising medical procedures, tests, or visits with health care providers that are undertaken for the purpose of promoting health, not for responding to patient signs, symptoms, or complaints."⁴ These services, typically delivered in health care settings, are often referred to as "secondary prevention." They are distinct from population- or community-based public health prevention activities, often referred to as "primary prevention," such as programs that assure clean water and safe food through regulation, or that discourage smoking through tax policy and public education campaigns.

Some clinical preventive services may both improve the patient's health and save money for payers. Most clinical preventive services, however, add to health care costs borne by the payer. When effective, these services may nonetheless be considered to provide a good value for their cost; that is, they are cost-effective.⁵ Whether or not a preventive measure is cost-effective

¹ See, for example, Kenneth E. Thorpe and David H. Howard, "The Rise In Spending Among Medicare Beneficiaries: The Role Of Chronic Disease Prevalence And Changes In Treatment Intensity," *Health Affairs*, vol. 25, no. 5 (August 22, 2006), pp. w378-w388.

² Congressional Budget Office, "Budget Options, Volume 1: Health Care," December 2008, p. 1, <http://www.cbo.gov/publications/collections/health.cfm>.

³ See, for example, Louise B. Russell, "Preventing Chronic Disease: An Important Investment, But Don't Count On Cost Savings," *Health Affairs*, vol. 28, no. 1 (January/February 2009), pp. 42-45.

⁴ Office of Technology Assessment (OTA), *Benefit Design: Clinical Preventive Services*, OTA-H-580, Washington, DC, September 1993, p. iii, available at <http://fas.org/ota/>.

⁵ In cost-effectiveness analyses, health benefits are commonly measured in non-monetary units, such as additional years of life gained or life years adjusted for quality (i.e., quality-adjusted life years—QALYs), and the end product is usually a ratio of the costs and benefits (e.g., dollars/QALY). For more information, see "Cost-effectiveness and Cost- (continued...)"

depends on the type of intervention and the population that is targeted. For example, an expensive screening test that is provided to the general population is likely to be very costly and provide limited clinical benefit if only a small fraction of those individuals would have become ill in the absence of the screening. But a less expensive intervention targeted at a population at high risk for a disease is likely to yield much greater value, and may even yield a net savings to the health care system.

In general, Medicare law authorizes the Secretary to cover services for the diagnosis and treatment of illness, while coverage of preventive services (i.e., services provided in the absence of symptoms) has generally required legislation. Although there is no statutory definition of “preventive services” that refers to these services collectively, Medicare law outlines specific coverage criteria for many preventive services, including factors such as the types of screening tests or services covered, and the age or risk profiles to which a service applies (see “Which Preventive Services Does Medicare Cover?”).

Over the years, Congress has sought expert advice to determine, for the purposes of Medicare coverage, whether a given preventive service is effective, and whether its clinical use is likely to benefit the patient without posing potential risks from the procedure itself. Current Medicare coverage of preventive services does not always comport with evidence-based recommendations of expert panels such as the U.S. Preventive Services Task Force (USPSTF). Congress provided the first administrative authority for the Secretary of Health and Human Services (HHS) to add coverage of additional preventive services in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110-275), if, among other things, such a service is recommended by the USPSTF (see “U.S. Preventive Services Task Force (USPSTF)”). A recent USPSTF recommendation regarding screening mammography has refocused congressional attention on the appropriate role of advisory panels with respect to Medicare coverage decisions.

This report examines Medicare coverage of clinical preventive services. First, it provides a brief overview of the Medicare program and history of congressional actions that added coverage of various clinical preventive services under Medicare, including, most recently, a comprehensive health assessment for new Medicare beneficiaries, and a new administrative authority of the Secretary of HHS to expand Medicare coverage of preventive services. Next, this report discusses how Medicare makes coverage decisions for its services, including preventive services. The report then discusses several advisory groups—in particular the USPSTF—and their recommendations regarding the effectiveness of clinical preventive services, Medicare coverage of these services, or related matters. Then it discusses two issues: (1) Do clinical preventive services help Medicare control costs? and (2) What is the utilization of Medicare clinical preventive services, and how might it be improved? This report then discusses current legislative proposals to reform the health care system, with respect to provisions regarding Medicare coverage of preventive services. Finally, the **Appendix** provides a comparison of Medicare coverage of preventive services with USPSTF recommendations for such services. This report will be updated as events warrant.

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benefit: Two Ways to Include Costs,” in CRS Report RL34208, *Comparative Clinical Effectiveness and Cost-Effectiveness Research: Background, History, and Overview*, by (name redacted).

Which Preventive Services Does Medicare Cover?

Overview of the Medicare Program

Medicare is the nation's federal insurance program that pays for covered health care services of qualified beneficiaries. It was established in 1965 under Title XVIII of the Social Security Act as a federal entitlement program to provide health insurance to individuals 65 and older, and has been expanded over the years to include permanently disabled individuals under 65. Medicare covers hospitalizations, physician services, prescription drugs, skilled nursing facility care, home health visits, and hospice care, among other services. The program is administered by the Centers for Medicare and Medicaid Services (CMS) in HHS and consists of four distinct parts (A through D).⁶

Overview of the Medicare Program

Part A (Hospital Insurance): covers inpatient hospital services, skilled nursing care, and home health and hospice.

Part B (Supplementary Medical Insurance): covers physician services, outpatient services, and home health and preventive services.

Part C (Medicare Advantage): is a private plan option for beneficiaries that covers all Part A and B services, except hospice. Many plans offer supplemental benefits.

Part D: covers prescription drugs.

Most persons aged 65 or older (and certain disabled persons under age 65) are automatically entitled to premium-free Medicare Part A which primarily covers hospitalizations. Generally, enrollment in Medicare Part B, which includes coverage of preventive services, is voluntary. All persons entitled to Medicare Part A may enroll in Part B by paying a monthly premium. In order to choose the Medicare Advantage (Part C) option, members must be entitled to Part A and enrolled in Part B.

Medicare Part B requires coverage of a number of specified clinical preventive services including a one-time initial preventive physical examination (IPPE); cardiovascular screening; certain periodic cancer screenings; bone mass measurements; diabetes screening, supplies and self-management training; medical nutrition therapy; and glaucoma tests.⁷ Medicare Part B also covers vaccines against influenza, pneumococcus, and, for individuals at increased risk, hepatitis B. Medicare Part D covers any FDA-licensed vaccine, when prescribed by a physician. Beneficiaries are responsible for an annual deductible (\$155 in 2010) and 20% of the costs of most Part B covered services. (Medicare covers the remaining 80%). However, Medicare law has been amended to waive cost-sharing for some, but not all, Part B covered preventive services.

Medicare Advantage (MA, Medicare Part C) offers beneficiaries an alternative way to obtain covered services through private health plans that are paid a per-person amount to provide

⁶ CRS Report R40425, *Medicare Primer*, coordinated by (name redacted).

⁷ Centers for Medicare and Medicaid Services, *Your Guide to Medicare's Preventive Services*, January 2009, <http://www.medicare.gov/Library/PDFNavigation/PDFInterim.asp?Language=English&Type=Pub&PubID=10110>.

Medicare covered benefits to enrollees. Participating MA plans must cover all services covered by original Medicare (except hospice), including Part B benefits, but may also offer coverage of additional services and have considerable flexibility in how they apply or waive cost-sharing.⁸ In general, MA plans cover some preventive services that original Medicare does not, and cost sharing may be less for such services. In 2008, all MA plans covered routine regular physical exams, in addition to a one-time IPPE. Additional preventive services that some MA plans covered included preventive dental services, vision and hearing benefits, expanded chiropractic and podiatry benefits, and selected health education and wellness benefits.⁹

History of Medicare Coverage of Clinical Preventive Services

Historically, Medicare has covered services to treat illnesses or injury covering only those expenses for items or services that fall within a defined Medicare benefit category, and excluding coverage of expenses that are “not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member....”¹⁰ Specifically, Medicare Part A and Part B excludes coverage of expenses for routine physical checkups as well as cosmetic surgeries, hearing aids, eyeglasses, routine foot care, routine dental care, and most immunizations (except as allowed in statute).¹¹ Preventive services were among those services categorically excluded from Medicare when the program was first established in 1965.¹² According to the IOM,

One rationale for excluding preventive services from Medicare was that they did not fit the traditional insurance model of providing coverage for expenses that are unpredictable (and thus cannot be budgeted) and substantial (and thus are a serious financial burden to individuals and families).¹³

IOM further noted that insurers also discouraged coverage for services that were “broad and ill-defined” such as routine physicals and health education or counseling.

Until recently, legislation was required to add coverage of a preventive service to Medicare Part B. Since 1980, when Congress required coverage of pneumococcal vaccination, Medicare law has been amended numerous times to add coverage of specified preventive services under Part B. Recently, Congress enacted the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110-275), which gave the Secretary of HHS limited authority to add coverage for new preventive services administratively, beginning in 2009. **Table 1** presents Medicare Part B preventive service benefits that have been added in statute.¹⁴

⁸ For further information on Medicare Advantage, see CRS Report R40374, *Medicare Advantage*, by (name redacted).

⁹ Gold, M. “Medicare Advantage Benefit Design: What Does It Provide, What Doesn’t It Provide, and Should Standards Apply?” March 2009, http://assets.aarp.org/rgcenter/health/2009_03_medicare.pdf.

¹⁰ Section 1862(a)(1)(A) of the Social Security Act [42 USC § 1395y(a)(1)(A)].

¹¹ Section 1862(a)(7) of the Social Security Act [42 USC § 1395y(a)(7)].

¹² Marilyn J. Field, Robert L. Lawrence, and Lee Zwanziger, *Extending Medicare Coverage for Preventive and Other Services*, Institute of Medicine, Committee on Medicare Coverage Extensions, Division of Health Care Services, (2000) National Academy Press, Washington, D.C., p. 16.

¹³ *Ibid.*

¹⁴ At this time, covered Medicare preventive services are established in statute and enumerated (among other covered services) in § 1861 of the Social Security Act [42 U.S.C. § 1395x].

Table 1. Legislative History of Medicare Coverage of Preventive Services

Year	Benefit(s) Added	Law
1980	Pneumococcal immunization	P.L. 96-611 Parental Kidnapping Prevention Act
1984	Hepatitis B immunization for beneficiaries at intermediate or high risk	P.L. 98-369 Deficit Reduction Act of 1984
1989	Pap smears	P.L. 101-239 Omnibus Budget Reconciliation Act of 1989
1990	Screening mammography	P.L. 101-508 Omnibus Budget Reconciliation Act of 1990
1993	Influenza immunization ^a	P.L. 100-203 Omnibus Budget Reconciliation Act of 1987 ^a
1997	Prostate and colorectal cancer screening; regular pelvic examinations in women; bone mass measurement for women at high risk for osteoporosis; and self-management training for beneficiaries with diabetes	P.L. 105-33 Balanced Budget Act of 1997
2000	Glaucoma screening; medical nutritional therapy for beneficiaries with diabetes or renal disease	P.L. 106-554 Consolidated Appropriations Act, 2001
2003	One-time “Initial Preventive Physical Examination” (IPPE); specified screening blood tests for beneficiaries at risk for cardiovascular disease or for diabetes	P.L. 108-173 Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)
2005	Ultrasound screening for abdominal aortic aneurysm in beneficiaries with certain risk factors	P.L. 109-171 Deficit Reduction Act of 2005
2008	Measurement of body mass index (BMI); discussion of end-of-life planning; administrative authority to add new preventive service benefits under specified conditions	P.L. 110-275 Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)

Source: Congressional Research Service.

- a. P.L. 100-203 required the Secretary of HHS to conduct a demonstration project and evaluation to determine if influenza vaccination coverage in Medicare would be cost-effective, and to provide such coverage unless it were determined that it would not be cost-effective. Influenza vaccination coverage began in 1993 after a finding of its potential cost-effectiveness. See Centers for Disease Control and Prevention (CDC), “Health Objectives for the Nation: Implementation of the Medicare Influenza Vaccination Benefit—United States, 1993,” *MMWR*, vol. 43, no. 42 (October 28, 1994), pp. 771-773.

Often with the passage of these laws, Congress also amended coverage of existing benefits, typically expanding eligibility, increasing the frequency of coverage, and/or covering the use of new screening technologies. (Additional information about the frequency and other aspects of current coverage for selected preventive services is provided in the **Appendix**.) Along the way, Congress has also eliminated beneficiary cost-sharing requirements for some, but not all, preventive services.¹⁵ As with all Medicare benefits, a beneficiary’s use of preventive service benefits is optional.

¹⁵ Current Medicare Part B coverage of preventive services, including cost-sharing requirements, if any, is presented in Centers for Medicare and Medicaid Services (CMS), *Quick Reference Information: Medicare Preventive Services*, January 2009, http://www.cms.hhs.gov/MLNProducts/downloads/MPS_QuickReferenceChart_1.pdf. See information about specific services at CMS Medicare “Prevention—General Information,” <http://www.cms.hhs.gov/PrevntnGenInfo>.

Two recent statutory expansions of Medicare preventive services coverage warrant special mention, and are discussed next. They are (1) coverage of an Initial Preventive Physical Examination (IPPE) and health risk appraisal; and (2) administrative authority of the Secretary of HHS to add coverage of new preventive services, under certain conditions.

Initial Preventive Physical: The “Welcome to Medicare” Exam

Medicare does not cover *routine* physical examinations to assess beneficiaries who do not have symptoms of an illness, or to develop a prevention plan. In 2003, in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108-173), Congress required Medicare to cover a *one-time* Initial Preventive Physical Examination (IPPE) and health risk appraisal (the “Welcome to Medicare” exam) for new Part B enrollees. CMS implemented coverage beginning January 1, 2005.¹⁶ Initially the benefit had to be used within six months of enrollment. In the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110-275), Congress extended the period of eligibility through the first year of enrollment, and modified the slate of services that were to be provided.

An IPPE must include the following:

- A complete patient history, including, at a minimum, a medical and surgical history; current medication and supplement use; family medical history; history of alcohol, tobacco, and illicit drug use; diet; and physical activity.
- A review of potential risk factors for depression and other mood disorders, using an appropriate and nationally recognized screening instrument.
- A review of functional ability and safety, including hearing; activities of daily living; falls risk; and home safety.
- A physical examination, including measurement of height, weight, blood pressure, and body mass index; visual acuity screening; and other factors deemed appropriate based on the individual’s medical and social history and current clinical standards.
- Provision of verbal or written information regarding end-of-life planning, upon the beneficiary’s consent, including general information, and whether or not the physician is willing to follow the beneficiary’s wishes as expressed in the advance directive.¹⁷
- Education, counseling, and referral, based on the results of the assessment, including diet counseling if the individual is overweight; education on the prevention of chronic diseases; and tobacco cessation counseling, if indicated.
- Completion of a brief written plan for the beneficiary to obtain appropriate screenings and other preventive services that are covered separately.¹⁸

¹⁶ CMS, “Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005; Final Rule,” 69 *Federal Register* 66282-66290, November 15, 2004.

¹⁷ For more information regarding end-of-life care and current health reform proposals, see CRS Report R40741, *End-of-Life Care Provisions in H.R. 3200*, by (name redacted).

¹⁸ CMS, *Medicare Preventive Services Quick Reference Information: The ABCs of Providing the Initial Preventive Physical Examination*, January 2009, http://www.cms.hhs.gov/MLNProducts/downloads/MPS_QRI_IPPE001a.pdf.

Some have advocated coverage of routine health care visits purposely to coordinate prevention and “wellness” services for Medicare beneficiaries, and to assure that follow-up care is provided as planned. Evidence of the effects of such an approach on the use of preventive services, health outcomes, or costs, has not been systematically studied. However, CMS is currently conducting a Senior Risk Reduction Program demonstration to “determine whether risk reduction programs (also referred to as health promotion, health management, demand management, and disease prevention programs) that have been developed and tested in the private sector can also be tailored to, and work well with, Medicare beneficiaries to improve their health and reduce avoidable health care utilization.”¹⁹

New Administrative Authority Under MIPPA

In MIPPA (P.L. 110-275), Congress provided the first administrative authority for the Secretary of HHS to expand Medicare coverage of preventive services, effective in January 2009. MIPPA authorizes the Secretary to add coverage of preventive services that are not already provided in statute, using the National Coverage Determination (NCD) process (see “How Does Medicare Determine Coverage?”), if the Secretary determines that three conditions are met, namely that the proposed preventive service is

- reasonable and necessary for the prevention or early detection of an illness or disability;
- recommended with a grade of A or B by the USPSTF;²⁰ and
- appropriate for individuals entitled to benefits under Medicare part A or enrolled under Medicare part B.²¹

MIPPA also authorizes the Secretary to consider cost in determining whether to add coverage of a preventive service, saying: “As part of the use of such [NCD] process, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such service and may take into account the results of such assessment in making such determination.”²² If coverage of a new preventive service is added under this authority, routine beneficiary cost-sharing requirements would generally apply. The Secretary is not authorized to waive these requirements.

The new authority allows the Secretary to extend coverage if the conditions of the provision are met. It does not require the Secretary to extend coverage solely based on a recommendation of the USPSTF. Nonetheless, there could be significant interest on the part of consumers, companies that make screening technologies, Members of Congress, and others, in adding coverage for a non-covered service if such service is recommended by the USPSTF.

¹⁹ CMS, “Medicare Program; Senior Risk Reduction Demonstration,” 71 *Federal Register* 49460-49461, August 23, 2006. See also CMS, “Senior Risk Reduction Program,” <http://www.cms.hhs.gov/demoprojectsevalrpts/MD/ItemDetail.asp?ItemID=CMS1190654>.

²⁰ The U.S. Preventive Services Task Force (USPSTF) makes clinical practice recommendations based on reviews of scientific evidence. See the subsequent section of this report, “U.S. Preventive Services Task Force (USPSTF).”

²¹ P.L. 110-275, the Medicare Improvements for Patients and Providers Act of 2008, § 101; Social Security Act § 1861(ddd) [42 U.S.C. § 1395x(ddd)].

²² *Ibid.*

In November, 2008, CMS, noting that the new authority is self-implementing, revised its regulations to reflect the statutory change.²³ The USPSTF strongly recommends HIV screening in all adolescents and adults (including older adults) who are at increased risk based on specified risk factors (see the **Appendix**). In March, 2009, CMS began a national coverage analysis (an initial step in the NCD process) to determine whether to cover HIV screening pursuant to the new authority.²⁴ In September, 2009, CMS proposed to cover voluntary HIV screening with an FDA-approved test for Medicare beneficiaries who are pregnant, or who may be at increased risk of infection based on several specified risk factors. On December 8, 2009, CMS published a final decision to cover voluntary annual screening of these beneficiaries, saying that coverage would be effective immediately.²⁵

CMS is reportedly also considering coverage analyses for alcoholism and depression screenings, aspirin therapy to prevent heart disease and stroke, and tobacco-cessation counseling.²⁶ Some of these are required as part of the IPPE, but the single encounter may not allow for these services or appropriate follow-up to be provided consistently. For example, a provider seeing a new Medicare patient with multiple chronic health conditions and multiple behavioral risk factors (e.g., smoking and excessive alcohol use) could have difficulty providing all of the required elements of the IPPE, and developing a thorough follow-up plan, in the single reimbursed visit.

How Does Medicare Determine Coverage?

To be eligible for payment under Medicare, items or services must meet the following three conditions: (1) the item or service must fall within a defined Medicare benefit category; (2) the item or service must be “reasonable and necessary” for diagnosis or treatment; and (3) the item or service is not statutorily excluded from coverage.²⁷ The statute vests the authority with the Secretary of HHS to determine what constitutes medically reasonable and necessary. Thus, the Secretary has the legal authority to specify which items or services are covered in a defined benefit category and under what conditions. As previously mentioned, Medicare law has been amended several times to add new coverage, including coverage of certain preventive health care services.

The process for Medicare coverage decisions for new technologies and procedures are made through two pathways. The first is through the National Coverage Determination (NCD) process. The second are those determinations made at the local level through Local Coverage

²³ 42 C.F.R. § 410.64. See CMS Final Rule at 73 *Federal Register* 69869-69871, November 19, 2008, regarding Medicare payment policy.

²⁴ CMS, “NCA Tracking Sheet for Screening for the Human Immunodeficiency Virus (HIV) Infection (CAG-00409N),” <https://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?from2=viewtrackingsheet.asp&id=229&>.

²⁵ *Ibid.* In addition to beneficiaries who are pregnant or at increased risk based on specified risk factors, screening would also be covered for beneficiaries who request it, whether or not they disclose having a specified risk factor.

²⁶ Ashley Richards, “CMS, Advocates Mull Possible National Prevention Services Decisions,” *InsideHealthPolicy.com*, May 15, 2009. Tobacco cessation counseling is currently covered by Medicare as a treatment service; i.e., a beneficiary must have symptoms of a tobacco-related illness in order for counseling to be covered. Covering tobacco cessation counseling as a preventive service would extend coverage to any beneficiaries who use tobacco products, whether or not they are symptomatic as a result.

²⁷ Social Security Act § 1862(a)(1). The law excludes some services and items from Part A and Part B coverage, such as routine physical checkups, most immunizations, cosmetic surgeries, hearing aids, eyeglasses, routine foot care, and routine dental care.

Determinations (LCDs).²⁸ The vast majority of these coverage policies are LCDs made by Medicare's claims administration contractors who, as of 2001, had made more than 9,000 separate policies.²⁹ These local contractors determine if a claim applies to a covered benefit and, if so, whether the medical service, procedure, or device is reasonable and necessary and therefore eligible for Medicare coverage.³⁰ According to CMS instructions, a service may be considered reasonable and medically necessary if it is safe and effective, not experimental, and appropriate in terms of duration and frequency. LCDs are only binding on a contractor's local service area. Therefore a service covered in one state may not be covered in a neighboring state, resulting in variations in Medicare coverage across the country.

At the national level, the National Coverage Determination (NCD) process is used by CMS' central office to issue national policy statements that grant, limit, or exclude Medicare coverage for a specific medical service, procedure, or device. The Coverage and Analysis Group of the Office of Clinical Standards and Quality at CMS is responsible for making NCDs. To date CMS has issued approximately 300 NCDs. CMS may issue a NCD in response to a formal request from an outside party such as a beneficiary, provider, or manufacturer; or the agency may internally decide to develop an NCD. As previously mentioned, under MIPPA the Secretary is authorized to add coverage of preventive services that are not already provided in statute, using the NCD process, if the Secretary determines that certain conditions (described above) are met. The agency has published guidance listing the conditions that may prompt the agency to consider developing an internal NCD for a Medicare item or service:³¹

- Providers, patients or other members of the public have raised significant questions about the health benefits of currently covered items or services.
- Interpretation of new evidence or re-interpretation of previously available evidence indicates that changes may be warranted in current policies.
- Local coverage policies are inconsistent or conflict with each other to the detriment of Medicare beneficiaries.
- Program integrity concerns have arisen under existing local or national policies such as variations in billing practices not related to variation in clinical need.

CMS's process for developing NCDs has generated concern over the years. Specifically, some observers have expressed that there is a lack of transparency in the agency's decision-making process for making Medicare coverage determinations.³² Beginning in 1999, CMS took a number

²⁸ According to the Medicare Payment Advisory Commission (MedPAC), Medicare can also develop and implement policies affecting the coverage of services through Medicare's provider manuals and program memorandums as well as coding requirements that can affect service coverage. MedPAC, Report to the Congress: Medicare Payment Policy, Appendix B, "An introduction to how Medicare makes coverage decisions," Washington, DC, March 2003, p. 245, <http://www.medpac.gov/>.

²⁹ Susan Bartlett Foote, "Focus on Locus: Evolution of Medicare's Local Coverage Policy," *Health Affairs*, vol. 22, no. 4 (July/August 2003), p. 138.

³⁰ LCDs also have the authority to make prospective coverage policies that apply in their jurisdiction if there is no applicable national coverage decision.

³¹ CMS, "Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination," April 11, 2006, http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=6.

³² U.S. General Accounting Office, *Medicare: Divided Authority for Policies on Coverage of Procedures and Devices Results in Inequities*, GAO-03-175, April 23, 2003, <http://www.gao.gov/new.items/d03175.pdf>. See also Sean R. Tunis, "Why Medicare Has Not Established Criteria for Coverage Decisions," *New England Journal of Medicine*, vol. 350, no. 21, (May 20, 2004).

of steps to increase transparency in its national coverage process including publishing coverage decisions on its website, establishing a Medicare Coverage Advisory Committee (MCAC, now the Medicare Evidence Development and Coverage Advisory Committee, MEDCAC) to conduct public meetings on coverage proposals, and publishing guidance documents to educate the public on the criteria and standards CMS uses when producing a NCD.³³ A few years later, Congress mandated certain requirements to improve the NCD process, such as implementing timelines in the development of NCDs and requiring public input in the development of NCDs.

Which Preventive Services Do Experts Recommend Medicare Cover?

Overview

Prior to the new authority in MIPPA, legislation was required to add Medicare Part B coverage for a new clinical preventive service. Since 1980, when it added the first preventive service benefit in Medicare, Congress has sought and received expert advice from several federal agencies or formal advisory bodies, as well as from the health care community, regarding the addition of new clinical preventive services to Medicare coverage. These panels have different mandates, and none is explicitly charged with evaluating preventive services for the purposes of Medicare coverage. Accordingly, the Medicare Payment Advisory Commission (MedPAC) has said, “Although the hearings and deliberations that have led to the introduction of new preventive benefits drew upon expert scientific advice, the process has been essentially ad hoc, and the resulting set of benefits does not reflect the current consensus of experts in the field of prevention and health promotion.”³⁴

This section discusses several expert panels that conduct science- or evidence-based analysis, or policy analysis, and develop recommendations regarding the use of preventive services in general, or in Medicare specifically. These panels vary in their administration, membership and oversight mechanisms; the parties to whom they report; and technical considerations, such as whether or not they consider cost in evaluating preventive services. While many of them make recommendations about the use of preventive services in clinical practice, none of them makes recommendations that are sufficiently detailed to translate directly into benefits design. For Medicare, that remains the shared purview of the Congress and the Secretary of HHS.

Table 2 provides brief descriptions of current expert panels discussed in this section.³⁵ Each panel is then discussed in more detail. The USPSTF is presented in the greatest depth because its recommendations may lead to expanded Medicare coverage of preventive services under the new

³³ For information on the NCD development process, see <http://www.cms.hhs.gov/DeterminationProcess/>.

³⁴ Medicare Payment Advisory Commission, *Report to the Congress: Assessing Medicare Benefits*, Appendix A, “Preventive Services and Medicare,” Washington, DC, June 2002, p. 69, <http://www.medpac.gov/>. MedPAC is a legislative branch agency established by the Balanced Budget Act of 1997 (P.L. 105-33) to advise Congress on issues affecting the Medicare program, including benefits, access to care, and quality of care. See also CRS Report R40915, *An Overview of Proposals to Establish an Independent Commission or Board in Medicare*, by (name redacted).

³⁵ Expert panels presented here are currently in operation and have assessed or made recommendations regarding one or more aspects of Medicare coverage of preventive services. The list of expert panels presented may not be comprehensive.

statutory authority of the HHS Secretary (discussed earlier), and under some proposals in pending House and Senate health reform legislation (see “Proposals in Health Reform Legislation”).

Table 2. Expert Panels That Make Recommendations Regarding Preventive Services

Panel	Brief Description
U.S. Preventive Services Task Force (USPSTF)	Assesses scientific evidence of the effectiveness and cost-effectiveness of clinical preventive services, and makes recommendations to the health care community regarding the use of these services by specific groups. Administered by the Agency for Healthcare Research and Quality (AHRQ).
Advisory Committee on Immunization Practices (ACIP)	Assesses scientific evidence of the effectiveness of immunizations, and makes recommendations to the Centers for Disease Control and Prevention (CDC) and the health care community regarding the use of these immunizations by specific groups. Administered by CDC.
Task Force on Community Preventive Services (TFCPS)	Assesses scientific evidence of the effectiveness and cost-effectiveness of community (i.e., population-based) preventive services (including interventions to improve the utilization of clinical preventive services), and makes recommendations to the public health and health care communities regarding the use of these services. Administered by CDC.
National Academy of Sciences (NAS) /Institute of Medicine (IOM)	Pursuant to congressional mandate, NAS or IOM panels have assessed scientific evidence of the effectiveness of specified clinical preventive services and made recommendations to Congress regarding Medicare coverage of these services.
Medicare Payment Advisory Commission (MedPAC)	Legislative branch agency, advises Congress on aspects of the Medicare program regarding benefits, access to care, and quality of care, usually involving diagnostic and treatment, rather than preventive, services. However, has recommended covering immunizations under Part B rather than Part D.
Medicare Evidence Development and Coverage Advisory Committee (MEDCAC)	Assesses scientific and technical evidence of the effectiveness of services, particularly new technologies, and advises CMS regarding their use. Assessments usually involve diagnostic and treatment, rather than preventive, services, but MEDCAC may evaluate preventive services pursuant to congressional mandate, or, in the future, pursuant to administrative authority of the HHS Secretary to expand coverage of preventive services under certain conditions. Administered by CMS.

Source: Congressional Research Service.

U.S. Preventive Services Task Force (USPSTF)

The U.S. Preventive Services Task Force (USPSTF) is administered by the HHS Agency for Healthcare Research and Quality (AHRQ).³⁶ It was first convened by the U.S. Public Health Service in 1984 to assess the scientific evidence for the effectiveness of a broad range of clinical preventive services, including screening, counseling, and preventive medications.³⁷ Congress provided explicit authority for the USPSTF when it established AHRQ in 1999,³⁸ saying that the

³⁶ AHRQ, “About USPSTF,” <http://www.ahrq.gov/clinic/uspstfab.htm>.

³⁷ The USPSTF does not evaluate or make recommendations regarding vaccines, but instead defers to the Advisory Committee on Immunization Practices (ACIP), discussed in the next section of this report.

³⁸ The agency had existed under different names previously. See “History and Legislative Authorities” in the AHRQ section of CRS Report RL34098, *Public Health Service (PHS) Agencies: Background and Funding*, coordinated by (name redacted).

USPSTF “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.”³⁹ The USPSTF appears to be exempt from requirements of the Federal Advisory Committee Act.⁴⁰

The USPSTF weighs evidence through systematic review of available literature on the use of preventive services in clinical practice, and its effects on health outcomes. Based on its reviews, the USPSTF gives one of four grades to each service it evaluates, or an “I Statement” if it finds that evidence is insufficient to support a recommendation. Grades are defined in the box below. “Benefit,” as used in the grade definitions, means a good result for the patient. *Only those services graded A or B are recommended by the USPSTF for routine use in medical practice.*

USPSTF Grades for Preventive Services

Grade A: The USPSTF recommends the service. There is high certainty that the net benefit is substantial. Providers should offer or provide this service.

Grade 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. Providers should offer or provide this service.

Grade C: The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small. Providers should offer or provide this service only if other considerations support the offering or providing the service in an individual patient.

Grade 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. Providers should discourage the use of this service.

I Statement: The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined. Providers should read the clinical considerations section of the USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

Source: AHRQ, USPSTF, “Grade Definitions After May 2007,” <http://www.ahrq.gov/clinic/uspstf/grades.htm>.

Until recently there was no statutory relationship between USPSTF recommendations and health care coverage decisions, although private health insurers have considered the recommendations when designing benefits packages for their insured populations. As noted earlier, in 2008 Congress provided, in MIPPA, the first administrative authority for the Secretary of HHS to expand Medicare coverage of preventive services, if (among other things) such services are recommended by the USPSTF. Several proposals in pending health reform legislation would also authorize or require the Secretary to expand or modify existing coverage of preventive services, and/or applicable cost-sharing requirements, according to recommendations of the USPSTF (see “Proposals in Health Reform Legislation”).

A comparison of current Medicare Part B coverage of preventive services for older adults with USPSTF recommendations is provided in the **Appendix**. Medicare coverage does not always correspond with USPSTF recommendations. For example, Medicare does not cover

³⁹ Public Health Service Act § 915(a); 42 U.S.C. § 299b–4(a).

⁴⁰ The Federal Advisory Committee Act (FACA) establishes certain requirements of committee membership, public access to proceedings, and other protections to assure that committees properly represent the public interest. 42 U.S.C. § 299b–4(a)(3) exempts the USPSTF from the provisions of Appendix 2 of title 5. A note to this section states that “Appendix 2 title 5 ... probably means the Federal Advisory Committee Act.” Although FACA is officially cited as 5 U.S.C. App., the United States Code Annotated, an unofficial version of the U.S. Code, cites the act as 5 U.S.C. App. 2.

recommended screening for sexually-transmitted infections in beneficiaries who may be at increased risk, or genetic screening for women whose personal or family history suggest that they may carry the so-called “breast cancer gene,” both services recommended by the Task Force.

In some cases, Medicare covers preventive services that the USPSTF recommends *against*. Perhaps the most controversial of these discrepancies regards the use of Prostate Specific Antigen testing (PSA, measured in a blood test) to screen men for prostate cancer. Congress added coverage for PSA screening to the Medicare benefits package in 1997. The USPSTF has never recommended PSA screening in older men, having previously found that there was insufficient evidence to justify such a recommendation. In 2008 the USPSTF reiterated its finding that there was insufficient evidence to assess the balance of benefits and harms of prostate cancer screening in men younger than 75 years of age. In addition, it recommended *against* PSA screening in men age 75 or older, finding that harm outweighed benefit in this group.⁴¹

In November, 2009, the USPSTF updated its recommendations regarding screening mammography for the detection of breast cancer. The Task Force had previously recommended that women receive screening mammograms every one to two years, beginning at age 40. Under the new guidelines, screening mammography for women between the ages of 40 and 49 is given a grade of C.⁴² It is no longer routinely recommended, although providers may recommend screening for some women in this age group based on individual assessments of risk. Screening of women between the ages of 50 and 74 years is recommended at an interval of every two years (grade B) and, according to the USPSTF, current evidence is insufficient to assess the additional benefits and harms of screening women 75 years or older (I Statement). The USPSTF “reasoned that the additional benefit gained by starting screening at age 40 years rather than at age 50 years is small, and that moderate harms from screening remain at any age.... The Task Force encourages individualized, informed decision making about when to start mammography screening.”⁴³ The Task Force considered, among other things, harms associated with false positive results (such as unnecessary biopsies) and with treatment of cancers that may not have progressed, balanced against lives saved through early detection of life-threatening cancers.

A number of patient and provider groups and some Members of Congress disagreed with the USPSTF’s stance in no longer recommending routine mammography screening of women in their forties. On November 18, 2009, HHS Secretary Sebelius issued a statement saying “The [USPSTF] is an outside independent panel of doctors and scientists who make recommendations. They do not set federal policy and they don’t determine what services are covered by the federal government.... The Task Force has presented some new evidence for consideration but our policies remain unchanged.”⁴⁴ Subsequently, the USPSTF announced that on December 4, 2009,

⁴¹ Harm arises not from the screening, but from diagnostic and treatment procedures that may be performed in response to abnormal results. According to the USPSTF, at this time, the PSA screening test does not reliably distinguish between cancers that are rapidly growing and life-threatening and those that are slow-growing and unlikely to threaten the patient within his lifetime. The older the patient, the less likely he is to benefit from intervention, in terms of length or quality of life, and the more likely he is to be harmed. This is the basis for the USPSTF recommendation against screening men age 75 or older. AHRQ, USPSTF, *Guide to Clinical Preventive Services: Screening for Prostate Cancer, Recommendation Statement*, August 2008, <http://www.ahrq.gov/clinic/uspstf08/prostate/prostaters.htm>. See also Michael J. Barry, “Screening for Prostate Cancer among Men 75 Years of Age or Older,” *New England Journal of Medicine*, vol. 359, no. 24 (December 11, 2008), pp. 2515-2516.

⁴² AHRQ, USPSTF, “Screening for Breast Cancer,” November 2009, updated December 2009, <http://www.ahrq.gov/clinic/uspstf/uspstfbrca.htm>.

⁴³ Ibid.

⁴⁴ HHS, “Secretary Sebelius Statement on New Breast Cancer Recommendations,” press release, November 18, 2009, (continued...)

it voted unanimously to update the language of its recommendation for women under 50 years of age to clarify the original and continued intent regarding provider consultation and individualized decision-making.⁴⁵

Several parties raised concerns that the revised USPSTF mammography recommendation was based on a cost analysis. Although Congress provided the USPSTF with explicit authority to consider cost-effectiveness in its recommendations, the group has not as yet incorporated this information into any of its recommendations, including the new mammography guidelines. Instead, for selected services, the USPSTF provides a separate analysis of cost-effectiveness.⁴⁶

USPSTF recommendations wield considerable influence in the health care community, in part because of the objectivity and rigor of the evidentiary process used to develop them. The process favors the stronger evidence that comes from narrow and well-controlled studies, such as randomized controlled trials. However, because the USPSTF limits its review to published evidence, its recommendations may lag behind trends in current medical practice. Also, the USPSTF has not evaluated service delivery mechanisms. For example, although there is considerable interest in options to coordinate patient care, including the potential merits of covering routine “wellness” exams under Medicare, the USPSTF has not published any evaluations of the effectiveness of routine physical examinations, health risk appraisals, or similar services, in improving health outcomes.

The USPSTF’s work is also limited to available clinical research, which often excludes older adults from study. For example, several clinical trials are underway in the United States and elsewhere to add to the knowledge base that physicians can use in interpreting PSA, biopsy, and other findings, in order to tailor the best approach for prostate cancer screening and management. These trials have not enrolled men age 75 or older, however, and therefore may not yield additional insights for the management of abnormal findings in this age group.⁴⁷

Finally, evidence of a clinical service’s effectiveness is only one element of benefits design. Available evidence may only address a one-time intervention, and therefore not inform decisions about frequency of coverage. Also, many USPSTF recommendations target services only to individuals at heightened risk for an illness or condition. It falls to other parties, with different expertise, to decide how such individuals would be identified for the purposes of reimbursement.

Advisory Committee on Immunization Practices (ACIP)

The Advisory Committee on Immunization Practices (ACIP) is a panel of experts in immunization and related fields, selected by the Secretary of HHS, who review scientific evidence and make recommendations to the Secretary and the Director of the Centers for Disease Control and Prevention (CDC) regarding the routine administration of vaccines to children,

(...continued)

<http://www.hhs.gov/news/>.

⁴⁵ AHRQ, USPSTF, “Screening for Breast Cancer,” November 2009, updated December 2009, <http://www.ahrq.gov/clinic/uspstf/uspstfbrca.htm>.

⁴⁶ AHRQ, USPSTF, “U.S. Preventive Services Task Force Procedure Manual,” AHRQ Publication No. 08-05118-EF, July 2008, p. 49, <http://www.ahrq.gov/clinic/uspstf08/methods/procmanual.htm>.

⁴⁷ Michael J. Barry, “Screening for Prostate Cancer among Men 75 Years of Age or Older,” *New England Journal of Medicine*, vol. 359, no. 24 (December 11, 2008), pp. 2515-2516.

adolescents, and adults in the U.S. civilian population.⁴⁸ The ACIP is administered by CDC, and is subject to provisions of the Federal Advisory Committee Act. Generally the ACIP reviews the use of vaccines that are licensed by the Food and Drug Administration (FDA), but it can also review and advise regarding the use of unlicensed vaccines under certain emergency circumstances. The ACIP considers cost-effectiveness as one component of its recommendations.

Medicare Part B currently covers three types of vaccinations⁴⁹ for its older beneficiaries: annual vaccination for influenza; initial vaccination for pneumococcus, and periodic boosters; and vaccination for hepatitis B in beneficiaries at high risk for infection (see the **Appendix**). In addition, Medicare Part D covers any FDA-licensed vaccine, upon prescription by a provider. (However, see the discussion below regarding the MedPAC recommendation that Congress permit coverage of appropriate preventive vaccinations under Part B instead of Part D.)

The USPSTF, discussed earlier, does not evaluate the effectiveness of immunizations, instead deferring to recommendations of the ACIP. The new authority provided in MIPPA, which allows the Secretary of HHS to add coverage of new preventive services in Medicare, is limited to services that are recommended by the USPSTF. The Secretary is not authorized to expand Medicare Part B coverage based on ACIP recommendations.

Task Force on Community Preventive Services (TFCPS)

The Task Force on Community Preventive Services (TFCPS) is a non-governmental panel of public health and prevention experts whose members are appointed by the CDC Director. It conducts systematic reviews of evidence, similar to the USPSTF process, but applied to population-based, rather than clinical, interventions.⁵⁰ Recommendations are published in the *Guide to Community Preventive Services*, which is updated continually in an electronic format.⁵¹

Many of the interventions evaluated by the TFCPS do not have a direct relationship to Medicare benefits. Examples include municipal approaches to control the commercial availability of alcohol; state laws regarding seat belt use; and the pricing of tobacco products. However, the TFCPS also studies approaches to improve the delivery and/or utilization of certain clinical preventive services, including some that are covered by Medicare. Examples include (1) client- and provider-oriented approaches to improve the utilization of breast, cervical, and colorectal cancer screening; (2) educational interventions to help patients understand cancer screening and make informed decisions with respect to their preferences; (3) approaches to the clinical management of diabetes, and self management education; and (4) home-, community- and clinic-based approaches to care for adults with depression.

⁴⁸ Jean C. Smith, Dixie E. Snider, and Larry K. Pickering, "Immunization Policy Development in the United States: The Role of the Advisory Committee on Immunization Practices," *Annals of Internal Medicine*, vol. 150, no. 1 (January 6, 2009), pp. 45-49, available at <http://www.cdc.gov/vaccines/recs/acip/default.htm>.

⁴⁹ Technically, vaccination and immunization are different. Both refer to the administration of substances called antigens, in order to raise immunity in the host. Vaccination originally referred specifically to immunization against smallpox, using vaccine virus. In common usage, and in this report, the terms are interchangeable.

⁵⁰ CDC, "The Task Force on Community Preventive Services," <http://www.thecommunityguide.org/about/task-force-members.html>.

⁵¹ CDC, "What is the Community Guide?" <http://www.thecommunityguide.org/index.html>.

As noted earlier, the new authority provided in MIPPA, which allows the Secretary of HHS to add coverage of new preventive services in Medicare, is limited to services that are recommended by the USPSTF. The Secretary is not authorized to expand Medicare coverage based on TFCPS recommendations.

National Academy of Sciences (NAS)/Institute of Medicine (IOM)

Congress has at times charged the National Academy of Sciences (NAS) or the Institute of Medicine (IOM) with evaluating the scientific merits of current or proposed Medicare coverage of preventive services. For example, in the Balanced Budget Act of 1997 (P.L. 105-33) Congress required HHS to fund studies of the short- and long-term benefits and costs to the Medicare program of providing coverage for skin cancer screening, medical nutrition therapy, and other specified services. An IOM expert committee found that there was insufficient evidence to recommend coverage of skin cancer screening, while an NAS expert committee recommended that medical nutrition therapy be covered for certain individuals, based on evidence of benefit.⁵²

Medicare Payment Advisory Commission (MedPAC)

The Medicare Payment Advisory Commission (MedPAC) is a legislative branch agency established by the Balanced Budget Act of 1997 (P.L. 105-33) to advise Congress on issues affecting the Medicare program.⁵³ The Commission's statutory mandate is quite broad. In addition to advising the Congress on payments to private health plans participating in Medicare (including Medicare Advantage plans) and providers in Medicare's traditional fee-for-service program, the commission is also tasked to examine issues such as changes in the health care delivery system, changes in the market for health care services, Medicare payment policies and their relationship to quality and access, and factors affecting the efficient delivery of health care services in different sectors (e.g., hospitals and skilled nursing facilities).⁵⁴ The Commission does not have executive responsibilities, and its recommendations are not binding on the Congress.

MedPAC has traditionally focused on diagnostic and treatment services, and has not evaluated the effectiveness of preventive services. Recently, however, the Commission has commented on the inclusion of appropriate preventive services, along with acute and chronic care services, in efforts to promote the use of primary care and improve care coordination.⁵⁵

MedPAC has commented on a specific aspect of preventive services coverage, namely coverage of preventive vaccinations. As noted earlier, Medicare Part B covers three types of vaccinations for older beneficiaries: annual vaccination for influenza; initial vaccination for pneumococcus, and periodic boosters; and vaccination for hepatitis B in beneficiaries at high risk for infection (see the **Appendix**). In addition, Medicare Part D covers any FDA-licensed vaccine, upon

⁵² Marilyn J. Field, Robert L. Lawrence, and Lee Zwanziger, *Extending Medicare Coverage for Preventive and Other Services*, Institute of Medicine, Washington, DC, 2000, <http://www.iom.edu/>; National Academy of Sciences, *The Role of Nutrition in Maintaining Health in the Nation's Elderly: Evaluating Coverage of Nutrition Services for the Medicare Population*, Washington, DC, 2000, <http://www.nap.edu>.

⁵³ Medicare Payment Advisory Commission, "About MedPAC," <http://www.medpac.gov/about.cfm>.

⁵⁴ See "Overview of the Medicare Policymaking Process" in CRS Report R40915, *An Overview of Proposals to Establish an Independent Commission or Board in Medicare*, by (name redacted).

⁵⁵ MedPAC, *Reforming the Delivery System*, Report to the Congress, June 2008, <http://www.medpac.gov/>.

prescription by a provider. MedPAC noted that in order to provide vaccinations, physicians must purchase the vaccine. They may then have difficulty recouping the costs for vaccines (other than the three covered under Part B) because they often do not have a way to bill Part D Plans. To address this, MedPAC recommended that Congress permit coverage of appropriate preventive vaccinations under Part B instead of Part D.⁵⁶

Medicare Evidence Development and Coverage Advisory Committee (MEDCAC)

The Medicare Evidence Development and Coverage Advisory Committee (MEDCAC, formerly the Medicare Coverage Advisory Committee) was established under broad authority in the Public Health Service Act⁵⁷ to advise CMS on aspects of Medicare coverage.⁵⁸ Its responsibilities include evaluating the effectiveness of interventions and assessing new technologies. Its work typically informs the CMS National Coverage Determination (NCD) process, through which decisions to cover new diagnostic and treatment services are made.

Because MEDCAC advises the executive branch rather than Congress, it has generally not been involved in evaluating preventive services, as expanding coverage for them usually requires legislation. A recent exception was MEDCAC's review of computed tomography (CT, or so-called "virtual colonoscopy") for colorectal cancer screening. In 1997, Congress gave the Secretary of HHS authority to cover additional screening tests for colorectal cancer after review through a national coverage analysis.⁵⁹ After conducting an analysis, which included an evidence review by MEDCAC, CMS concluded in 2009 that the "evidence is inadequate to conclude that CT colonography is an appropriate colorectal cancer screening test under §1861(pp)(1) of the Social Security Act. CT colonography for colorectal cancer screening remains noncovered."⁶⁰

Given the new authority in MIPPA, which authorizes the Secretary to add coverage of preventive services through the NCD process, MEDCAC may be asked to review additional proposals to expand coverage of preventive services in the future. (See the earlier section "New Administrative Authority Under MIPPA.")

Can Utilization of Preventive Services Control Medicare Costs?

There is good evidence, and general agreement, that many preventive services can improve health care quality by preventing illness, disability, and death. It is less clear, however, whether

⁵⁶ MedPAC, *Promoting Greater Efficiency in Medicare*, Report to the Congress, June 2007, pp. 166-167, <http://www.medpac.gov/>.

⁵⁷ Public Health Service Act § 222 [42 U.S.C. § 217a].

⁵⁸ CMS, "Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)," http://www.cms.hhs.gov/FACA/02_MEDCAC.asp.

⁵⁹ Balanced Budget Act of 1997, P.L. 105-33, § 4104.

⁶⁰ CMS, "Decision Memo for Screening Computed Tomography Colonography (CTC) for Colorectal Cancer," (CAG-00396N), May 12, 2009, <https://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?from2=viewdecisionmemo.asp&id=220&>.

expanded coverage or utilization of clinical preventive services could stem cost growth or produce savings for the Medicare program or other payers of health services. For example, covering screening services for early detection of serious conditions such as cancer may not be cost-saving for payers. Because it is usually not possible to know beforehand which patients will go on to develop a serious illness, screenings must be delivered to large numbers of people who would never have developed the condition.⁶¹ Also, prevention interventions may be shown to yield a net cost in the short term, but a net saving over a longer period, or vice versa. Cost analyses that cover longer time periods may be more useful, but they are also more difficult to conduct, and are therefore less common.⁶²

The National Commission on Prevention Priorities, a private research group, developed a priority ranking for clinical preventive services, based on measurements of under-utilization and cost-effectiveness. (The latter is a measure of the value of the service, defined by its cost in relation to its benefits.⁶³) Although the Commission determined that a number of services were cost-effective, only a few of them were cost-saving. These were discussing aspirin use for adults at risk of heart attack; screening for tobacco-use, followed by brief counseling and referral for drug therapy; vision screening in adults age 65 and older; and certain immunizations. Several other effective and underutilized services—including screenings for cholesterol, blood pressure, and several types of cancer—were found to yield a net cost.⁶⁴

The Congressional Budget Office (CBO) recently commented on proposals to expand coverage of preventive services, saying, with respect to federal costs, “Although different types of preventive care have different effects on spending, the evidence suggests that for most preventive services, expanded utilization leads to higher, not lower, medical spending overall.”⁶⁵ The agency reviewed several studies that demonstrated improved quality and outcomes associated with increased use of certain preventive services, but that increased the costs for the payer. CBO provided several explanations, including, as mentioned above, the costs associated with screenings in individuals who would not go on to develop the disease being screened. CBO also noted that some proposals could encourage a shift to federal coverage for services that individuals already receive under private insurance, thereby yielding a net cost to the government without a concurrent improvement in health care quality.

CBO also noted that a preventive service that is particularly effective and increases longevity would probably incur a net cost for the Medicare and Social Security programs, because it would prevent a portion of premature mortality among beneficiaries, who would then use program

⁶¹ See, for example, Congressional Budget Office, *The Budgetary Effects of Expanding Governmental Support for Preventive Care and Wellness Services*, Letter to the Honorable Nathan Deal, August 7, 2009, pp. 1-2,

⁶² See, for example, Elbert. S. Huang et al., “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*, vol. 28, no. 5 (September 1, 2009).

⁶³ For more information, see Partnership for Prevention, *What Policymakers Need to Know About Cost Effectiveness*, Washington, DC, 2001, http://www.prevent.org/images/stories/Files/publications/Cost_Effectiveness.pdf.

⁶⁴ Michael V. Maciosek et al., “Priorities Among Effective Clinical Preventive Services: Results of a Systematic Review and Analysis,” *American Journal of Preventive Medicine*, vol. 31, no. 1 (2006), pp. 52-61, <http://www.prevent.org/images/stories/clinicalprevention/article%201669p.pdf>.

⁶⁵ Congressional Budget Office, *The Budgetary Effects of Expanding Governmental Support for Preventive Care and Wellness Services*, Letter to the Honorable Nathan Deal, August 7, 2009, <http://www.cbo.gov/ftpdocs/104xx/doc10492/08-07-Prevention.pdf>.

benefits for a longer period of time.⁶⁶ The agency has cited influenza vaccination as an example.⁶⁷ In this vein, in 1987 Congress required the Secretary of HHS to conduct a demonstration project to determine if covering influenza vaccination would be cost-effective for Medicare, and to provide coverage if such a finding was made. Congress explicitly prohibited consideration of the effects of reduced mortality in the cost-effectiveness analysis.⁶⁸ Influenza vaccination coverage began in 1993 after the finding of its potential cost-effectiveness under this qualified definition.

CBO, the National Commission on Prevention Priorities, and others note that although preventive services do not always yield cost savings for the government or other payers, those services that are effective and beneficial should nonetheless be considered for reimbursement based on their value. Because covering some effective preventive services, or waiving cost-sharing for others that are already covered, could incur net costs for the Medicare program, Congress may choose to consider raising revenues, or offsetting the costs in Medicare or through other federal programs, if it wishes to expand Medicare coverage of these services under current budget rules.

There has also been some debate about whether prevention activities funded through other means could improve health outcomes and control costs in Medicare. Such activities include health care services provided to the “pre-Medicare” population, and population-based health promotion (“primary prevention”) interventions, such as expansions in the primary care workforce, smoking cessation campaigns, and other public health measures.

CMS has an interest in the health status of the “pre-Medicare” population for at least two reasons. First, behaviors that could improve the health of the Medicare population—such as smoking cessation, proper diet, and exercise—are desirable earlier in life, rather than being initiated upon enrollment. Second, Medicare may experience a wave of morbidity and costs associated with care for new enrollees whose diseases advanced as a result of deferral of care prior to enrollment.⁶⁹

A recently published study by a public health advocacy group, based on an economic model it developed, estimated that \$3 billion (\$10 per capita) in federal spending on effective population-based health promotion activities in the United States could lead to savings of more than \$5 billion for Medicare within five years.⁷⁰ Congress provided \$650 million to expand these types of activities in the American Recovery and Reinvestment Act (ARRA, P.L. 111-5).⁷¹ CBO has not provided its own estimate of the possible effects of such discretionary spending on Medicare, noting that scorekeeping rules prohibit consideration of the effects of federal discretionary spending proposals on federal mandatory spending.⁷²

⁶⁶ Ibid.

⁶⁷ Congressional Budget Office, *Key Issues in Analyzing Major Health Insurance Proposals*, “Expanding the Use of Clinical Preventive Services,” Washington, DC, December 2008, pp. 136-139, <http://www.cbo.gov>.

⁶⁸ P.L. 100-203, Omnibus Budget Reconciliation Act of 1987, § 4071(b).

⁶⁹ See, for example, a study showing that previously uninsured new Medicare beneficiaries had greater morbidity, requiring more intensive and costlier care, compared with previously insured new beneficiaries. J. Michael McWilliams, Ellen Meara, and Alan Zaslavsky, et al., “Use of Health Services by Previously Uninsured Medicare Beneficiaries,” *New England Journal of Medicine*, vol. 357 (July 12, 2007), pp. 143-153.

⁷⁰ Trust for America’s Health, *Prevention for a Healthier America: Investments in Disease Prevention Yield Significant Savings, Stronger Communities*, July 2008, <http://healthieramericans.org/healthier-america-project/>.

⁷¹ See “Disease Prevention” in CRS Report R40181, *Selected Health Funding in the American Recovery and Reinvestment Act of 2009*, coordinated by (name redacted).

⁷² Congressional Budget Office, *The Budgetary Effects of Expanding Governmental Support for Preventive Care and Wellness Services*, Letter to the Honorable Nathan Deal, August 7, 2009, pp. 6-7, <http://www.cbo.gov/ftpdocs/104xx/> (continued...)

Can Utilization of Medicare Preventive Services Be Improved?

Expanding Medicare coverage to include preventive services is meant to improve quality of care, and, ideally, to improve health status among beneficiaries. However, preventive services that are effective can usually improve health status only for those beneficiaries who use them.⁷³

The Government Accountability Office (GAO) analyzed patient and physician survey data from 2000 and found that although nine in ten Medicare beneficiaries visited a physician at least once during the year, many of them did not receive recommended preventive services such as vaccinations and cancer screenings.⁷⁴ Similarly, a review of Medicare claims data for 2001 showed that even when all patient visits for the year were included, fewer than half of Medicare beneficiaries received all five of the studied preventive services to which they were entitled.⁷⁵ A study of 2001 Medicare Current Beneficiary Survey (MCBS) data found that the use of clinical preventive services was lower among beneficiaries with certain characteristics, including lower income; Black race; and dual enrollment in Medicare and Medicaid.⁷⁶ Authors of these studies report that Medicare beneficiaries were not always aware that they were at risk for certain illnesses, that they could potentially benefit from preventive services, and that such services were covered by Medicare.

Beneficiary cost sharing has been shown to decrease the utilization of preventive services in some contexts, including the use of screening mammography by beneficiaries in Medicare managed care plans.⁷⁷ Based on an evidence review, the Task Force on Community Preventive Services (TFCPS) recommends reducing beneficiaries' out-of-pocket costs in order to improve utilization of screening mammography. However, the TFCPS found that there was insufficient evidence to make the same recommendation regarding screenings for cervical or colorectal cancer.⁷⁸

The TFCPS has reviewed evidence of additional means to improve cancer screening rates, and recommends patient and client reminder systems and certain education and outreach approaches,

(...continued)

doc10492/08-07-Prevention.pdf.

⁷³ Vaccinations against communicable diseases are an exception. Others may benefit, in addition to the person who is vaccinated, if disease transmission is curtailed.

⁷⁴ U.S. Government Accountability Office, *Medicare Preventive Care: Most Beneficiaries Receive Some but Not All Recommended Services*, GAO-04-1004T, September 21, 2004, <http://www.gao.gov>.

⁷⁵ Hoangmai Pham, Deborah Schrag, and J. Lee Hargraves, et al., "Delivery of Preventive Services to Older Adults by Primary Care Physicians," *JAMA*, vol. 294, no. 4 (July 27, 2005), pp. 473-481. The services studied were eye exams in diabetics, screening mammography in women age 65-74 years, colon cancer screening in beneficiaries age 65-79 years, and vaccinations for influenza and pneumococcus in beneficiaries age 65 and older. In addition, about 56% of beneficiaries with diabetes received monitoring of hemoglobin A1c levels to which they were entitled.

⁷⁶ Ronald J. Ozminkowski, Ron Z. Goetzel, and David Schechter, et al., "Predictor of Preventive Service Use Among Medicare Beneficiaries," *Health Care Financing Review*, vol. 27, no. 3 (Spring 2006).

⁷⁷ Peter B. Bach, "Cost Sharing for Health Care—Whose Skin? Which Game?," *New England Journal of Medicine*, vol. 358, no. 4 (January 24, 2008), pp. 411-413.

⁷⁸ Task Force on Community Preventive Services, "Recommendations for Client- and Provider-directed Interventions to Increase Breast, Cervical, and Colorectal Cancer Screening," *American Journal of Preventive Medicine*, vol. 35, suppl. 1 (2008), pp. S21-25. See also CDC, TFCPS, <http://www.thecommunityguide.org/cancer/screening/client-oriented/ReducingOutOfPocketCosts.html>.

based on evidence of their effectiveness.⁷⁹ There have been numerous efforts by executive branch agencies, sometimes directed by Congress, to improve utilization of preventive services through patient and provider education campaigns and other means. For example, the IOM National Cancer Policy Forum, with funding from CDC, has studied approaches to improve the utilization of colorectal cancer screening.⁸⁰

The Medicare Initial Preventive Physical Examination (IPPE) offers an opportunity for providers to review beneficiaries' health status and recommend or deliver appropriate preventive services. The IPPE may not assure optimal utilization of covered services, however. It is currently covered only once in a beneficiary's lifetime. Some have advocated more frequent health care encounters designed to encourage, coordinate, and deliver recommended preventive services. However, the effectiveness of this approach, whether in improving either utilization of services or health outcomes, has not been systematically studied.

Proposals in Health Reform Legislation

This section summarizes provisions regarding Medicare-covered preventive services in comprehensive Senate- and House-passed bills on health reform. Each bill contains provisions that could result in the expansion (and in the case of the Senate bill, the curtailment) of coverage of certain preventive services under Medicare, in some cases in accordance with recommendations of the USPSTF. In addition, each bill would authorize or reauthorize the current functions of the USPSTF, to be administered in each case by AHRQ.

The House is preparing to vote on H.R. 3590, as passed by the Senate, and on an accompanying reconciliation bill (H.R. 4872).⁸¹ The reconciliation bill would change several controversial elements in H.R. 3590 and otherwise amend the underlying legislation so that its budgetary impact meets the reconciliation instructions in last year's budget resolution.⁸² However, it would not alter the Medicare preventive services provisions in H.R. 3590, which are summarized below. If the House approves H.R. 3590, it will be sent to the President to be signed into law. The reconciliation measure, if approved by the House, would then be taken up by the Senate.

Unless otherwise specified, references in the summaries to "the Secretary" mean the Secretary of HHS. This section will be updated to reflect major legislative actions.

⁷⁹ Ibid.

⁸⁰ Institute of Medicine, *Implementing Colorectal Cancer Screening. Workshop Summary*, December 11, 2008, <http://www.iom.edu/CMS/26765/60428.aspx>.

⁸¹ H.R. 4872, the Reconciliation Act of 2010, was reported by the House Budget Committee on March 17, 2010 (H.Rept. 111-443). The full House will consider reconciliation language offered as an amendment in the nature of a substitute to H.R. 4872. The full text of the amendment is at http://docs.house.gov/rules/hr4872/111_hr4872_amndsub.pdf.

⁸² Under the FY2010 budget resolution (S.Con.Res. 13), a health reform reconciliation bill must reduce the federal deficit by \$1 billion over the period FY2009 through FY2014, as determined by the Congressional Budget Office.

Senate-Passed H.R. 3590: The Patient Protection and Affordable Care Act

On December 24, 2009, the Senate passed an amended version of the Patient Protection and Affordable Care Act (H.R. 3590). The bill is a comprehensive health reform proposal that represents an amalgam of separate measures reported by the Committee on Finance and the Committee on Health, Education, Labor, and Pensions (HELP).⁸³ It contains the provisions below regarding Medicare coverage of preventive services. CBO has scored most, but not all, of these proposals as incurring a net cost for the Medicare program.⁸⁴

An adopted amendment could affect the implementation of several provisions in the Senate bill. On December 2, 2009, the Senate adopted S.Amdt. 2808, introduced by Senator Vitter, which would provide that “for the purposes of this Act, and for the purposes of any other provisions of law, the current recommendations of the [USPSTF] regarding breast cancer screening, mammography, and prevention shall be considered the most current other than those issued in or around November 2009.”⁸⁵ As noted earlier, in November 2009, the USPSTF updated its recommendation regarding the use of mammography for breast cancer screening. Previously, the panel had recommended routine screening for women beginning at age 40; it now recommends that routine screening begin at age 50. The Vitter amendment, which would appear to negate the November 2009 recommendations, could affect provisions in the health reform bills that link USPSTF recommendations to coverage as such coverage would apply to screening mammography for female beneficiaries between age 40 and 49.

Section 4103, “Medicare coverage of annual wellness visit providing a personalized prevention plan,” as amended by Section 10402(b) of the bill, would amend SSA Section 1861 to require that Medicare Part B cover, beginning in 2011, personalized prevention plan services, including a comprehensive health risk assessment. The personalized plan could include several specified elements, among them: review and update of medical and family history; a 5- to 10-year screening schedule and referral for services recommended by the USPSTF and ACIP; a list of identified risk factors and conditions, and a strategy to address them; lists of all medications currently prescribed and all providers regularly involved in the patient’s care; review or referral for testing and treatment of chronic conditions; and cognitive impairment assessment. All enrolled beneficiaries would be eligible for personalized prevention plan services once every year, without any cost sharing. During the first year of Part B enrollment, beneficiaries could receive only the initial preventive physical examination (IPPE). Beneficiaries could receive personalized prevention plan services each year thereafter provided that they have not received either an IPPE or personalized prevention plan services within the preceding 12 months.

Section 4104, “Removal of barriers to preventive services in Medicare,” as amended by Section 10406 of the bill, would, effective in 2011, amend SSA Section 1861 to define preventive services covered by Medicare to mean a specified list of currently covered services, including colorectal

⁸³ Provisions in this bill regarding preventive services are described in CRS Report R40943, *Public Health, Workforce, Quality, and Related Provisions in H.R. 3590, as Passed by the Senate*, coordinated by (name redacted) and (name redacted). CRS reports summarizing additional provisions in this bill are available at <http://crs.gov/pages/SubIssue.aspx?CLIID=3746&parentID=13>.

⁸⁴ CBO, “H.R. 3590, Patient Protection and Affordable Care Act, Cost Estimate for the Bill as Passed by the Senate on December 24, 2009,” March 11, 2010, p. 10 of 16, <http://www.cbo.gov/doc.cfm?index=11307&zzz=40511>.

⁸⁵ This provision amends Sec. 1001 of the bill, which would, among other things, create a new PHSA Sec. 2713.

cancer screening services even if diagnostic or treatment services were furnished in connection with the screening. The list also would include the IPPE, as well as the personalized prevention plan services that would be covered pursuant to Section 4103 of the bill. Coverage would continue to be subject to all criteria that apply to each preventive service covered under current law. In addition, this section would amend SSA Section 1833 to waive beneficiary coinsurance requirements for most preventive services, requiring Medicare to cover 100% of the costs. Services for which no coinsurance would be required are the IPPE, personalized prevention plan services, any additional preventive service covered under the Secretary's administrative authority, and any currently covered preventive service (including medical nutrition therapy, and excluding electrocardiograms) if it is recommended with a grade of A or B by the USPSTF. The section would generally waive the application of the deductible for the same types of preventive services noted above for which coinsurance would be waived. It would not, however, waive the application of the deductible for any additional preventive service covered under the Secretary's administrative authority.

Section 4105, "Evidence-based coverage of preventive services in Medicare," would, effective January 1, 2010, authorize the Secretary to modify the coverage of any currently covered preventive service (including services included in the IPPE, but not the IPPE itself), to the extent that the modification is consistent with USPSTF recommendations. This section also would allow the Secretary to withhold payment for any currently covered preventive service graded D (i.e., not recommended) by the USPSTF. The enhanced authority would not apply to services furnished for the purposes of diagnosis or treatment (rather than as preventive services furnished to asymptomatic patients).⁸⁶

In addition, **Section 4003**, "Clinical and Community Preventive Services Task Forces," would reauthorize current authority for the USPSTF (calling it the "Preventive Services Task Force"), requiring the Task Force to 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*. The provision also states that "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." This section would also codify the existing TFCPS.

House-Passed H.R. 3962: The Affordable Health Care for America Act

On November 7, 2009, by a vote of 220-215, the House passed a comprehensive health reform bill, the Affordable Health Care for America Act (H.R. 3962).⁸⁷ The legislation, introduced by Representative Dingell on October 29, 2009, is based on an earlier measure, the America's Affordable Health Choices Act of 2009 (H.R. 3200), which was jointly developed and reported by the House Committees on Ways and Means, Energy and Commerce, and Education and Labor. The legislation contains the following provisions regarding Medicare coverage of preventive

⁸⁶ CBO has scored this provision as incurring a net savings for the Medicare program. See footnote 84.

⁸⁷ Provisions in this bill regarding preventive services are described in CRS Report R40892, *Public Health, Workforce, Quality, and Related Provisions in H.R. 3962*, coordinated by (name redacted). CRS Reports summarizing additional provisions in this bill are available at <http://crs.gov/pages/SubIssue.aspx?CLIID=3746&parentID=13>.

services. CBO has scored most of these proposals as incurring a net cost for the Medicare program.⁸⁸

Section 1305, “Coverage and waiver of cost-sharing for preventive services,” would amend Section 1861 of the Social Security Act (SSA) to define “Medicare covered preventive services” as a specified list of currently covered services, and any services subsequently covered under the Secretary’s administrative authority. Coverage would be subject to conditions and limitations that currently apply to each listed service, except that any cost-sharing (deductible and/or coinsurance) that currently applies would be waived.

Section 1306, “Waiver of deductible for colorectal cancer screening tests regardless of coding, subsequent diagnosis, or ancillary tissue removal,” would amend SSA Section 1833 to clarify that coinsurance and the deductible would be waived for colorectal cancer screening services even if diagnostic or treatment services were furnished concurrently as a result of findings of the screening.

Section 1310, “Expanding access to vaccines,” would provide Medicare Part B coverage for all federally recommended vaccines, defined as any approved vaccine that is recommended by the CDC upon advice from the Advisory Committee on Immunization Practices (ACIP).

Section 1311, “Expansion of Medicare-covered preventive services at Federally Qualified Health Centers”(FQHCs), would amend SSA Section 1861 to provide that FQHCs may receive Medicare reimbursement for Medicare covered preventive services (as defined in Section 1305 of this bill).

Section 1313, “Recognition of certified diabetes educators as certified providers for purposes of Medicare diabetes outpatient self-management training services,” would amend SSA Section 1861 to designate certain certified diabetes educators as Medicare-certified providers of covered diabetes self-management training (DSMT) services. A “certified diabetes educator” would be defined as an individual who meets specified criteria, including certification by a “recognized certifying body,” which also would be defined.

In addition, **Section 2301** would establish new Sections 3131 and 3132 in the Public Health Service Act (PHSA), requiring the Secretary to establish two task forces: a Task Force on Clinical Preventive Services (comparable to the USPSTF), to be administered by AHRQ, and a Task Force on Community Preventive Services, to be administered by CDC. (The latter provision would codify the existing TFCPS.) Each task force would be required, among other things, to review evidence regarding the benefits, effectiveness, appropriateness, and costs of clinical or community preventive services, respectively, and to develop and disseminate recommendations for the use of such services.

⁸⁸ CBO, “Revised Cost Estimate for the Bill as Passed by the House of Representatives,” November 20, 2009, p. 5 of 12, <http://www.cbo.gov/doc.cfm?index=10741&zzzz=39846>.

Appendix. Comparison of Medicare Coverage of Preventive Services with USPSTF Recommendations for Older Adults

The following **Table A-1** compares currently covered Medicare preventive services with recommendations of the U.S. Preventive Services Task Force (USPSTF) for older adults. For simplicity, this analysis is limited to services and recommendations for individuals age 65 years or older, the core age group for Medicare eligibility. Individuals younger than 65 years who may also be Medicare eligible include persons with certain disabilities or with end-stage renal disease. For these individuals, additional USPSTF recommendations—such as those for younger age groups or for pregnant women—may apply, but are not presented in this table.

Services listed in the table include any services that are either (1) currently covered as preventive services under Medicare Part B; or (2) recommended (i.e., with a Grade of A or B) by the USPSTF for adults including or limited to those age 65 years or older. In some cases both criteria apply.

Listed USPSTF recommendations include, in parentheses, the USPSTF Grades for the service, as follows:

- Grade A: The USPSTF recommends the service, based on high certainty that the net benefit is substantial.
- Grade B: The USPSTF recommends the service, based on high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.
- Grade C: The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small.
- Grade D: The USPSTF recommends against the service, based on moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits; or
- I Statement: The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, or of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

Only those services graded A or B are recommended for routine clinical use. The year in which the USPSTF published its recommendations regarding the specific service is also provided in parentheses. As with clinical recommendations in general, specific USPSTF recommendations may not be appropriate for individuals with certain risk factors or other special considerations, or may be modified by certain clinical considerations.

Table A-1. For Adults Age 65 or Older, Comparison of Preventive Services Covered by Medicare Part B with USPSTF Recommendations for Older Adults

Service	Medicare Coverage for Eligible Beneficiaries Age 65 and Older	USPSTF Recommendation for Older Adults
EXAMINATION, HEALTH ASSESSMENT		
Initial physical examination, health risk assessment	Medicare covers a one-time Initial Preventive Physical Examination (IPPE), also called the “Welcome to Medicare” exam, within the first 12 months of Part B coverage. The benefit is to include examination and/or discussion as follows: (1) review of the patient’s medical and social history with attention to modifiable risk factors (smoking cessation, alcohol use, and diet counseling for those who are overweight are explicitly mentioned in program materials); (2) review of potential risk factors for depression; (3) review of functional ability and level of safety; (4) a physical examination, to include measurement of height, weight, blood pressure, body mass index, and visual acuity; (5) information about end-of-life planning; and (6) education, counseling, and referral based on the results of the review and evaluation services described in the previous five components, and a brief written plan, such as a checklist for obtaining the appropriate screening and/or other Part B preventive services. ^a	The USPSTF has not specifically evaluated the effectiveness of one-time or periodic physical examinations. However, in addition to specific recommendations displayed later in this table, it does recommend the following screening and counseling services (to be provided in primary care settings) that correspond to some of the health risk assessment and counseling activities in the Medicare IPPE. For example, the USPSTF <i>strongly recommends</i> : (1) blood pressure screening; and (2) discussing aspirin use with adults who are at increased risk for heart disease. The USPSTF <i>recommends</i> : (1) depression screening; (2) screening and counseling for alcohol misuse; (3) intensive behavioral dietary counseling for adults with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease; (4) for obese adults, intensive counseling and behavioral interventions to promote sustained weight loss; and (5) screening and counseling for adults at high risk for HIV and certain sexually transmitted diseases (See “Infectious Diseases / Immunizations” below).
CARDIOVASCULAR DISEASE		
Electrocardiogram (“EKG”)	Prior to 2009, a screening EKG was covered for all patients as part of the IPPE. After January 1, 2009, a one-time screening EKG became optional, requiring a referral based on a finding from the IPPE.	<i>Recommends against</i> the routine use of EKGs to screen for cardiovascular disease. (Grade D, 2004)
Lipid disorders	All beneficiaries who are asymptomatic (i.e., have no symptoms) for cardiovascular disease are entitled to blood testing for cholesterol, high-density lipoproteins, and triglycerides every five years.	<i>Strongly recommends</i> screening for lipid disorders in women age 45 and older if they are at increased risk for coronary heart disease, and in men age 35 and older. The optimal screening interval is uncertain. (Grade A, 2008)
Abdominal aortic aneurysm (AAA) screening	One-time screening is covered for beneficiaries at risk, based on risk factors identified during the IPPE.	<i>Recommends</i> one-time screening by ultrasonography in men age 65 to 75 who have ever smoked. (Grade B, 2005) <i>No recommendation for or against</i> screening in men age 65 to 75 who have never smoked. (Grade C, 2005) <i>Recommends against</i> routine screening in women. (Grade D, 2005)

Service	Medicare Coverage for Eligible Beneficiaries Age 65 and Older	USPSTF Recommendation for Older Adults
Aspirin for the Prevention of Cardiovascular Disease	No corresponding benefit. Discussion of aspirin use for this purpose could be provided during the IPPE, but CMS guidance does not explicitly mention this.	<i>Strongly recommends</i> the use of aspirin for this purpose in men age 45 to 79 years, and women age 55-79 years, unless contraindicated by risk of gastrointestinal bleeding. (Grade A, 2009) <i>Insufficient evidence</i> to assess the use of aspirin for this purpose in men and women 80 years or older. (I Statement, 2009) <i>Recommends against</i> the use of aspirin for this purpose in men younger than age 45 and women younger than age 55. (Grade D, 2009)
CANCER SCREENING		
Breast cancer	All female beneficiaries age 40 or older are entitled to coverage for annual screening mammography.	<i>Recommends</i> biennial screening mammography for women aged 50 to 74 years. (Grade B, 2009) <i>Insufficient evidence</i> to assess the additional benefits and harms in women 75 years or older. (I Statement, 2009)
Medication to prevent breast cancer	Although this service is not explicitly discussed in Medicare's literature on preventive services, it may be implicit in the intent of the IPPE to include evaluation of such health risks and appropriate counseling.	<i>Recommends</i> that clinicians discuss preventive medication with women at high risk for breast cancer and at low risk for adverse effects from the medications. Clinicians should inform patients of the potential benefits and harms of preventive medication. (Grade B, 2002)
Genetic risk for breast and ovarian cancer	No corresponding Medicare benefit.	<i>Recommends</i> 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. (Grade B, 2005)
Cervical and vaginal cancer	For women who are at high risk for cervical or vaginal cancer, Medicare covers annual screening pelvic exams and pap tests. For women who are not at high risk, Medicare covers screening pelvic exams and pap tests every 2 years. ^b	<i>Recommends against</i> routinely screening women older than age 65 for cervical cancer if they have had adequate recent screening with normal Pap smears and are not otherwise at high risk for cervical cancer. The recommendation against screening may be modified by certain clinical considerations. (Grade D, 2003)
Colorectal cancer	Coverage is based on beneficiary's risk for colorectal cancer, which is based on family and personal history of colon cancer, precancerous conditions, or other abnormalities. Various procedures may be covered at various intervals, depending upon risk. For example: Medicare covers one screening fecal occult blood test annually, regardless of risk. For beneficiaries not at high risk for colorectal cancer, Medicare covers: one flexible sigmoidoscopy every 4 years (unless the individual has had a colonoscopy in the preceding 10 years); one barium enema every 4 years; or one screening colonoscopy every 10 years. Generally, screening intervals for these tests are shortened for beneficiaries considered at high risk. ^c	<i>Recommends</i> 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. (Grade A, 2008) <i>Recommends against</i> routine screening for colorectal cancer in adults age 76 to 85 years. There may be considerations that support colorectal cancer screening in individual patients. (Grade C, 2008) <i>Recommends against</i> screening for colorectal cancer in adults older than age 85 years. (Grade D, 2008)

Service	Medicare Coverage for Eligible Beneficiaries Age 65 and Older	USPSTF Recommendation for Older Adults
Prostate cancer	All male beneficiaries age 50 and older are entitled to coverage for annual digital rectal examinations and blood tests for Prostate Specific Antigen (PSA).	<i>Insufficient evidence</i> to assess the balance of benefits and harms of prostate cancer screening using PSA in men younger than age 75 years. (I Statement, 2008) <i>Recommends against</i> screening for prostate cancer using PSA in men age 75 years or older. (Grade D, 2008)
OSTEOPOROSIS SCREENING		
Bone mass measurement	Beneficiaries considered to be at risk for osteoporosis are entitled to coverage for screening bone mass measurement every 2 years, or more frequently if medically necessary.	<i>Recommends</i> that women aged 65 or older be screened routinely for osteoporosis. The optimal screening interval is not known. (Grade B, 2002)
GLAUCOMA SCREENING		
Glaucoma screening	Beneficiaries designated as high risk—those with diabetes, a family history of glaucoma, African-Americans age 50 or older, or Hispanic-Americans age 65 or older—are entitled to coverage of annual glaucoma screening.	<i>Insufficient evidence</i> to recommend for or against screening adults for glaucoma. (I Statement, 2005)
METABOLIC, NUTRITIONAL, AND ENDOCRINE CONDITIONS		
Diabetes screening	For beneficiaries with certain risk factors for diabetes, but not diagnosed with pre-diabetes, Medicare covers one screening per year. For beneficiaries diagnosed with pre-diabetes, Medicare covers two screenings per year. This benefit is not available to beneficiaries who have been diagnosed with diabetes.	<i>Recommends</i> screening for type 2 diabetes in asymptomatic adults with sustained blood pressure (either treated or untreated) greater than 135/80 mm Hg. The optimal screening interval is not known. (Grade B, 2008) <i>Insufficient evidence</i> to assess the balance of benefits and harms of screening for type 2 diabetes in asymptomatic adults with blood pressure of 135/80 mm Hg or lower. (I Statement, 2008)
Diabetes self-management training (DSMT)	Certain beneficiaries at risk for complications from diabetes, recently diagnosed with diabetes, or previously diagnosed with diabetes, are entitled to coverage of up to 10 hours of initial training within a continuous 12-month period, and in subsequent years, up to 2 hours of follow-up training annually, provided a physician certifies that DSMT is needed.	The USPSTF does not address diabetes self management. However, the CDC Task Force on Community Preventive Services recommends, based on demonstrated effectiveness, that health systems implement diabetes disease management programs (which often include self-management training), and that diabetes self-management education be provided to adults with type 2 diabetes in community settings, such as community centers, faith institutions, and libraries. ^d
Medical nutrition therapy	Beneficiaries diagnosed with diabetes or renal disease are entitled to coverage of 3 hours of one-on-one counseling the first year, and 2 hours for each subsequent year. Additional counseling may be available with physician referral, based on need.	<i>Recommends</i> intensive behavioral dietary counseling for adult patients with hyperlipidemia and other known risk factors for cardiovascular and diet-related chronic disease. This would include a diagnosis of diabetes. Intensive counseling can be delivered by primary care clinicians or by referral to other specialists, such as nutritionists or dietitians. (Grade B, 2003) The USPSTF does not address nutrition therapy in patients with renal disease.

Service	Medicare Coverage for Eligible Beneficiaries Age 65 and Older	USPSTF Recommendation for Older Adults
MENTAL AND BEHAVIORAL HEALTH		
Depression screening	Depression screening is a required element of the one-time IPPE (described above). ^a It is not covered as a separate service.	<i>Recommends</i> screening adults for depression when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up. (Grade B, 2009)
Alcohol misuse	Review of the beneficiary's history of alcohol use is a required element of the one-time IPPE (described above). ^a It is not covered as a separate service.	<i>Recommends</i> screening and behavioral counseling interventions to reduce alcohol misuse by adults, in primary care settings. (Grade B, 2004)
Smoking / tobacco cessation	Beneficiaries who use tobacco products <i>and have a related disease or adverse health effect or other factor for increased risk</i> are entitled to coverage for two cessation attempts per year, involving intermediate or intensive counseling, but not pharmacotherapy. Medicare Part D covers smoking cessation pharmacotherapy prescribed by a physician, but not over-the-counter treatments such as nicotine patches or gum.	<i>Strongly recommends</i> that clinicians screen all adults for tobacco use and provide tobacco cessation interventions (including screening, brief behavioral counseling, and pharmacotherapy delivered in primary care settings) for those who use tobacco products. (Grade A, 2009)
INFECTIOUS DISEASES		
Sexually transmitted infections (STIs)	Medicare does not cover STI screening in asymptomatic individuals.	The USPSTF has evaluated evidence and issued findings regarding several STIs, and recommends (with Grades of A or B) screening certain individuals for syphilis, chlamydia, and/or gonorrhea if they are at increased risk, based on factors including gender, age, sexual activity, and/or pregnancy. In addition, the USPSTF <i>recommends</i> high-intensity behavioral counseling to prevent sexually transmitted infections (STIs) for all sexually active adolescents and for adults at increased risk for STIs. (Grade B, 2008)
Human Immunodeficiency Virus (HIV)	Medicare covers annual voluntary HIV screening of beneficiaries at increased risk for HIV infection, based on specified risk factors, and beneficiaries who request screening. ^e	<i>Strongly recommends</i> HIV screening for all pregnant women, and for all adolescents and adults at increased risk based on sexual activity and/or other specified risk factors. Age is not among the specified risk factors, i.e., the recommendation applies based on risk, regardless of age. (Grade A, 2005) ^f
IMMUNIZATIONS		
Influenza	Medicare covers annual influenza vaccination for all beneficiaries.	The USPSTF defers to the Advisory Committee on Immunization Practices (ACIP) regarding immunization recommendations. ^g
Pneumococcus	Medicare covers one-time pneumococcal vaccination for all beneficiaries, and one booster after 5 years for those at high risk.	As above.
Hepatitis B	Medicare covers one-time hepatitis B vaccination for beneficiaries at high risk.	As above.

Source: Adapted by Congressional Research Service from Centers for Medicare and Medicaid Services (CMS), “Quick Reference Information: Medicare Preventive Services,” January 2009, http://www.cms.hhs.gov/MLNProducts/downloads/MPS_QuickReferenceChart_1.pdf; “Prevention—General Information,” <http://www.cms.hhs.gov/PrevntionGenInfo/>; and “Prevention,” <http://www.cms.hhs.gov/home/medicare.asp>; and Agency for Healthcare Research and Quality, “U.S. Preventive Services Task Force (USPSTF) Guide to Clinical Preventive Services,” electronic version, as of March 2010, <http://www.ahrq.gov/clinic/uspstfix.htm>.

- a. Details of services covered as part of the IPPE are available at CMS “Medicare Preventive Services Quick Reference Information: The ABCs of Providing the Initial Preventive Physical Examination,” http://www.cms.hhs.gov/MLNProducts/downloads/MPS_QRI_IPPE001a.pdf; and “Welcome to Medicare Exam,” <http://www.cms.hhs.gov/WelcometoMedicareExam/>.
- b. Patient risk status is defined at CMS, “Cervical Cancer Screening,” <http://www.cms.hhs.gov/CervicalCancerScreening/>.
- c. Details of Medicare coverage of colorectal cancer screening are available at CMS “Colorectal Cancer Screening,” <http://www.cms.hhs.gov/ColorectalCancerScreening/>.
- d. Centers for Disease Control and Prevention (CDC), *Guide to Community Preventive Services*, Diabetes Prevention and Control, <http://www.thecommunityguide.org/diabetes/>. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110-275) did not provide authority for the Secretary of HHS to establish new Medicare preventive services benefits based on recommendations from the Guide to Community Preventive Services, as it did for USPSTF recommendations (see below).
- e. MIPPA § 101 authorizes the Secretary of HHS to add coverage of additional preventive services under Medicare Part B if, among other things, a service is recommended by the USPSTF with a grade of A or B. On December 8, 2009, CMS added coverage of annual voluntary HIV screening for beneficiaries at increased risk of HIV infection, beneficiaries who request screening, and beneficiaries who are pregnant. CMS, “NCA Tracking Sheet for Screening for the Human Immunodeficiency Virus (HIV) Infection (CAG-00409N),” <https://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?from2=viewtrackingsheet.asp&id=229&>.
- f. In September 2006, the CDC recommended universal HIV screening for all individuals between age 13 and 64 years, regardless of recognized risk factors. CDC, “Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-care Settings,” *MMWR*, vol. 55 (RR-14) (September 22, 2006), pp. 1-17. In November 2006, the USPSTF reviewed the CDC recommendation and reaffirmed its own “Grade C” finding, namely that it makes no recommendation regarding HIV screening for non-pregnant adolescents and adults who are not at increased risk for HIV infection.
- g. For the ACIP’s current immunization recommendations, see the CDC National Immunization Program website at <http://www.cdc.gov/vaccines/recs/acip/default.htm>. MIPPA did not provide authority for the Secretary of HHS to establish new Medicare preventive services benefits based on ACIP recommendations, as it did for USPSTF recommendations. The ACIP recommends that all older adults receive influenza vaccine annually, which Medicare Part B covers. The ACIP also recommends that they receive a single dose of pneumococcal vaccine, and be revaccinated periodically under certain conditions. Medicare Part B covers one-time pneumococcal vaccination, and one booster for those at high risk. The ACIP recommends hepatitis B vaccination in this age group only if certain other risk factors are also present. Medicare covers hepatitis B vaccination for beneficiaries at high risk. Additional immunizations recommended by the ACIP for this age group, but not covered under Medicare Part B, include a one-time dose of herpes zoster (Shingles) vaccine; two doses of varicella (Chicken Pox) vaccine if the person is not already likely to be immune; and a tetanus/diphtheria booster vaccine every ten years. (See Centers for Disease Control and Prevention, “Recommended Adult Immunization Schedule—United States, 2009,” *MMWR*, vol. 57, no. 53 (January 9, 2009), pp. Q-1–Q-4.) Medicare Part D, established in law in 2003, covers any vaccine that is approved by the Food and Drug Administration, and its administration, upon a prescription.

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Acknowledgments

(name redacted), Analyst in Health Insurance and Financing (7-....), contributed to the section titled “How Does Medicare Determine Coverage?”

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