United States Government Accountability Office

GAO

Report to Congressional Committees

December 2011

MEDICARE

Many Factors, Including Administrative Challenges, Affect Access to Part D Vaccinations

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Highlights

Highlights of GAO-12-61, a report to congressional committees

Why GAO Did This Study

Vaccinations can prevent diseases and improve the quality of life for Medicare beneficiaries. Vaccinations for flu and pneumonia are covered by Medicare's Part B physician and outpatient service benefit. Since 2006, Medicare's Part D prescription drug benefit covers other routinely recommended vaccinations, such as the shingles vaccination. Part D typically contracts with pharmacies, but not physicians, for covered vaccinations. The Patient Protection and Affordable Care Act required GAO to study Medicare beneficiary access to routinely recommended vaccinations covered under Part D. GAO examined (1) the extent to which beneficiaries have received Part D-covered vaccinations, (2) factors affecting beneficiary access to vaccinations, and (3) any findings and recommendations of government agencies and other stakeholders to increase access to Part D-covered vaccinations. To do this, GAO (1) analyzed Centers for Disease Control and Prevention (CDC) national health survey data and Medicare data; (2) surveyed physicians, pharmacies, and state beneficiary assistance programs nationwide; and (3) convened a facilitated discussion with stakeholder groups.

What GAO Recommends

GAO recommends that CMS explore options and take appropriate steps to address administrative challenges, such as physicians' difficulty verifying beneficiary coverage and billing for Part D-covered vaccinations. The Department of Health and Human Services concurred with GAO's recommendation.

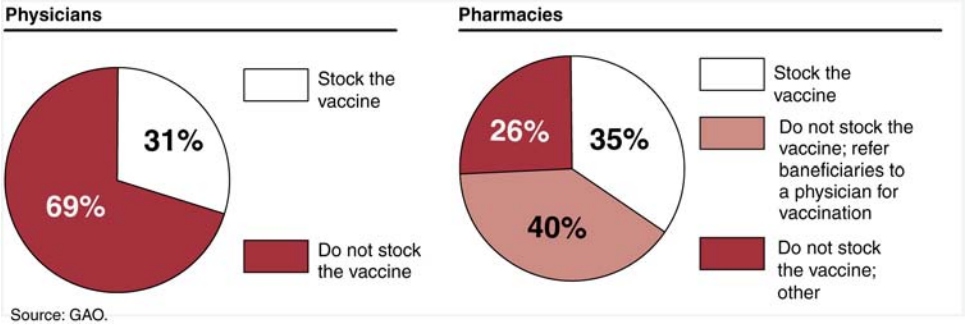
View GAO-12-61. For more information, contact Katherine Iritani at (202) 512-7114 or iritanik@gao.gov.

What GAO Found

Many of the almost 22 million Medicare beneficiaries age 65 and older who were enrolled in Medicare Part D in 2009 did not receive the routinely recommended vaccinations covered by Part D. CDC national survey data for 2009 show that 11 percent of Medicare beneficiaries age 65 and older had received a shingles vaccination and 53 percent had received a Td (tetanus and diphtheria) vaccination—the routinely recommended vaccinations covered under Part D. Medicare data for 2007 through 2009 show that relatively few Part D beneficiaries received these vaccinations under Part D—5 percent for shingles and less than 1 percent for Td or Tdap (which includes protection against pertussis). These data suggest that beneficiaries either received vaccinations prior to enrolling in Medicare or, once enrolled, used other health coverage or paid out of pocket for these vaccinations.

A multitude of factors affect beneficiaries' access to routinely recommended Part D-covered vaccinations, particularly the low percentage of physicians and pharmacies that stock the relatively new shingles vaccine (see figure). Most physicians do not stock the shingles vaccine due to factors such as the cost of purchasing a supply and Part D billing challenges. More than half of physicians refer beneficiaries to pharmacies to purchase the vaccine—which may require beneficiaries to transport the vaccine back to the physician to be administered. Physicians recommend shingles vaccinations less often than other vaccinations, and even when they recommend them, beneficiaries often decline them. At the same time, due in part to a limited supply of the shingles vaccine, only about one-third of pharmacies nationwide stock it. Beneficiaries' cost sharing—which averaged $57 for a shingles vaccination in 2009—and challenges with obtaining reimbursement from Part D plans were other reported deterrents to beneficiaries' obtaining Part D vaccinations.

Physicians' and Pharmacies' Stocking Practices for the Shingles Vaccine, 2010



Source: GAO.

Note: Percentages may not total to 100 percent due to rounding.

Many stakeholders—government agencies, advisory bodies, and professional organizations—have raised concerns about the administrative challenges associated with Part D and have recommended actions to improve access to Part D vaccinations. The Centers for Medicare & Medicaid Services has issued guidance on a number of approaches to help address administrative challenges, but stakeholders report that additional steps are needed, including broader use of web-based systems, that could provide real-time access to allow physicians to verify beneficiary coverage and bill Part D plans.

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Abbreviations

ACIP	Advisory Committee on Immunization Practices
CBO	Congressional Budget Office
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
HHS	Department of Health and Human Services
IOM	Institute of Medicine
LIS	low-income subsidy
MedPAC	Medicare Payment Advisory Commission
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
NHIS	National Health Interview Survey
PPACA	Patient Protection and Affordable Care Act
SHIP	State Health Insurance Assistance Program
SSA	Social Security Act
Td	tetanus and diphtheria vaccine
Tdap	tetanus, diphtheria, and acellular pertussis vaccine
USPSTF	U.S. Preventive Services Task Force

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United States Government Accountability Office
Washington, DC 20548

December 15, 2011

The Honorable Max Baucus
Chairman
The Honorable Orrin G. Hatch
Ranking Member
Committee on Finance
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable David Camp
Chairman
The Honorable Sander M. Levin
Ranking Member
Committee on Ways and Means
House of Representatives

Vaccinations have the potential to prevent diseases and improve the quality of life for individuals enrolled in Medicare—the federal health insurance program that covered nearly 38 million beneficiaries age 65 and older in 2009.[1] Upon its establishment in 1965, Medicare generally covered treatment services if a beneficiary became ill or injured. Over time, Congress broadened Part B—which pays for physician and other outpatient medical services—to cover certain preventive services, including vaccinations to protect against pneumonia and influenza.[2] When

[1]Medicare also provides coverage to certain individuals with disabilities as well as individuals with end-stage renal disease.

[2]Medicare began Part B coverage for vaccinations to prevent pneumonia (pneumococcal vaccine) in 1980 and began coverage for vaccinations to protect against influenza in 1993. In addition, Part B covers vaccinations against hepatitis B for certain individuals and vaccinations incident to the treatment of an injury or incidence of exposure—for example, vaccinations to treat potential exposure to tetanus as the result of an injury, such as after a patient stepped on a rusty nail that may have exposed him or her to the disease.

the Part D outpatient prescription drug benefit began in January 2006, it expanded Medicare coverage to encompass all routinely recommended vaccinations that were not specifically covered under Part B.[3] As of August 2011, the primary routinely recommended vaccinations covered under Part D are the onetime vaccination to prevent shingles—a viral infection that produces a painful, blistering rash and affects nearly 1 million individuals each year[4]—and vaccinations to help prevent tetanus and diphtheria (Td vaccine) or tetanus, diphtheria, and pertussis (Tdap vaccine).[5] These vaccines can greatly reduce the burden of preventable disease in older Americans. For example, the shingles vaccine—first approved in 2006—has been shown to reduce the overall incidence of shingles in older adults by about half and to reduce the incidence of postherpetic neuralgia by about two-thirds.[6] Due in part to the importance of routinely recommended vaccinations covered under Part D as preventive services, long-standing interest exists in ensuring that beneficiaries are able to access them. In addition, newly developed vaccines that become recommended for routine administration to Medicare beneficiaries would also be covered under Part D.

A number of stakeholders are involved in ensuring that Medicare beneficiaries have access to routinely recommended vaccinations, including those covered under Part D. The Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention

[3]In this report, we use the term routinely recommended vaccinations to indicate adult vaccinations that are recommended by the Centers for Disease Control and Prevention and its Advisory Committee on Immunization Practices (ACIP) for most people within an age group. For more information on ACIP vaccination recommendations, see http://www.cdc.gov/vaccines/recs/acip/ (accessed Sept. 29, 2011).

[4]Shingles, also called herpes zoster, results from a reactivation of the virus that causes chicken pox. The risk of developing shingles increases after age 50.

[5]Tetanus is a serious disease (also known as lockjaw) that causes painful tightening of the muscles and leads to death in about 1 in 10 cases; diphtheria is a disease that can lead to breathing problems, paralysis, heart failure, and potentially death; and pertussis is the disease commonly known as whooping cough. Both the Td and Tdap vaccinations protect against tetanus and diphtheria, and the Tdap vaccination protects against pertussis as well. After the initial vaccinations, Td vaccination is recommended as a booster every 10 years and Tdap as a onetime replacement for a Td booster. Unless otherwise indicated, references to the Td/Tdap vaccinations in this report refer to vaccinations administered as a preventive measure and not in response to exposure.

[6]Postherpetic neuralgia is a persistent, debilitating pain at the site of the shingles rash that can last for months or years after the blisters have healed.

(CDC) and its Advisory Committee on Immunization Practices (ACIP) make recommendations for adult immunizations. HHS's Centers for Medicare & Medicaid Services (CMS) administers Medicare, including Part D. CMS contracts with private Part D plan sponsors that offer prescription drug plans to Medicare beneficiaries. Although the plans may differ in the drugs they cover and in the pharmacies they use, all Part D plans must cover all licensed vaccines not covered under Part B.[7] Other stakeholders include physicians, who traditionally administer vaccinations, and pharmacists, who dispense vaccines and can administer them in most states.

The Patient Protection and Affordable Care Act (PPACA) required us to study the ability of Medicare beneficiaries age 65 and older to access routinely recommended vaccinations covered under Medicare Part D.[8] This report discusses (1) the extent to which Medicare beneficiaries have received the routinely recommended vaccinations covered under Part D; (2) factors that could affect Medicare beneficiaries' access to the routinely recommended vaccinations covered under Part D; and (3) any findings and recommendations from government agencies, advisory bodies, professional organizations, and other stakeholders to increase access to routinely recommended vaccinations under Part D.

To determine the extent to which Medicare beneficiaries age 65 and older[9] have received the routinely recommended vaccinations covered under Part D, we (1) obtained information on recommended vaccinations for adult Medicare beneficiaries by reviewing recommendations of and interviewing officials from CMS, CDC, ACIP, and the National Vaccine

[7]Plans may differ in the drugs they cover within specific therapeutic categories, but all Part D plans must cover all licensed vaccines not available under Part B, when used for a medically accepted indication.

[8]Pub. L. No. 111-148, § 4204(e), 124 Stat. 119, 572 (2010).

[9]This report focuses on Medicare beneficiaries age 65 and older. In 2009, over 97 percent of individuals age 65 and older were enrolled in Medicare. Nearly all Americans age 65 and older are automatically enrolled in Medicare Part A, and in this report, the term Medicare beneficiaries refers to those age 65 and older in Medicare Part A. Part A provides hospital insurance that helps cover inpatient care in hospitals and hospices, related posthospital care in skilled nursing facilities, and home health services. When we refer to those beneficiaries age 65 and older enrolled in Medicare Part D, we call them Part D beneficiaries. About 58 percent of Part A beneficiaries are also enrolled in a Part D outpatient prescription drug plan.

Advisory Committee;[10] (2) analyzed data from the 2007 National Immunization Survey and the 2008 and 2009 National Health Interview Surveys (NHIS)[11] administered by CDC's National Center for Health Statistics on the percentage of adults age 65 and older, both with and without Part D coverage, who reported ever receiving a shingles vaccination or receiving a Td vaccination in the prior 10 years;[12] (3) analyzed Part D data from 2007 through 2009, focusing on data for shingles and Td/Tdap vaccinations;[13] and (4) obtained enrollment data on Medicare beneficiaries with Part D coverage. To assess the reliability of the CDC and Medicare data, we interviewed knowledgeable officials, reviewed relevant documentation, and compared our results to published data. We determined that these data were sufficiently reliable for the purposes of our engagement.

To identify factors that could affect Medicare beneficiaries' access to the routinely recommended vaccinations covered under Part D, we (1) reviewed relevant laws, regulations, and guidance on coverage of

[10]The National Vaccine Advisory Committee makes recommendations to the Director of HHS's National Vaccine Program, which is responsible for coordinating and ensuring collaboration among federal agencies involved in vaccination and immunization activities.

[11]The National Immunization Survey is conducted jointly by CDC's National Center for Health Statistics and the National Center for Immunization and Respiratory Diseases. The survey began data collection in 1994 to monitor childhood immunization coverage and periodically surveys the status of adult immunizations. NHIS annually provides information on the health status of the U.S. civilian noninstitutionalized population through confidential interviews conducted in households. It is the nation's largest household health survey, providing data for analyses of health trends; determining barriers to care; and comparing health status, health-related behaviors, and risk factors across racial and ethnic populations.

[12]While our focus in this report is on Medicare beneficiaries age 65 and older, we also examined CDC data on adults age 60 to 64 because ACIP recommends shingles and Td/Tdap vaccinations for these ages and vaccinations received at ages 60 to 64 would still be effective when beneficiaries enrolled in Medicare at age 65.

[13]Under Part D, every time a beneficiary fills a Part D prescription, the plan must submit a summary record called a prescription drug event to CMS containing specified information, such as the beneficiary identification number, date of service, provider identifier, dispensed drug, and beneficiary cost-sharing amount. Our analysis included prescription drug event data for beneficiaries age 65 and older from 2007 through 2009 and excluded data for beneficiaries in employer plans, religious fraternal benefit plans, CMS demonstration plans, and programs of all-inclusive care for the elderly—because not all beneficiaries are allowed to enroll in those plans and programs. NHIS data from 2009 were the most recent available at the time of our review, and we used 2009 Medicare data to be comparable.

routinely recommended adult vaccinations under Medicare; (2) surveyed nationally representative samples of 6,500 primary care physicians—family and internal medicine physicians—and 1,500 pharmacies to obtain information on common provider practices for the shingles and Td/Tdap vaccinations covered under Part D and, for comparison, the pneumococcal vaccination covered under Part B; (3) surveyed State Health Insurance Assistance Programs (SHIP)—state agencies that provide counseling and assistance to Medicare beneficiaries—for all 51 states, including the District of Columbia, to obtain information on any beneficiary questions and difficulties related to vaccinations covered under Part D;[14] (4) analyzed Part D data from 2007 through 2009, focusing on reimbursement methods and beneficiaries' cost sharing for Part D vaccinations; (5) interviewed a judgmental selection of nursing home administrators who represent members of the American Health Care Association and the American Association of Homes and Services for the Aging; and (6) interviewed officials from six Part D plan sponsors that cover almost 40 percent of all Part D beneficiaries. We also examined information on the extent to which Medicare beneficiaries under the age of 65 and those residing in nursing homes face unique barriers to Part D vaccinations.

To examine any findings and recommendations from government agencies, advisory bodies, professional organizations, and other stakeholders to improve access to routinely recommended vaccinations under Medicare Part D, we (1) interviewed relevant stakeholders, including officials representing government agencies, advisory bodies, provider professional organizations, Part D plan sponsors, and Medicare beneficiary advocacy organizations; (2) contracted with the National Academy of Sciences to have the Institute of Medicine (IOM) convene a group of key stakeholder to discuss vaccinations covered under Part D; and (3) conducted a literature review of articles from peer-reviewed journals, as well as documents, letters, reports, and other materials provided by federal agencies, advisory bodies, and industry organizations. In addition, we compared the proposals identified through the interviews, discussion, and literature review to responses to our provider and SHIP surveys.

[14]We refer to the District of Columbia as a state throughout this report.

We conducted this performance audit from September 2010 to December 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. (For more information on our scope and methodology, see app. I.)

Background

Medicare Enrollment and Coverage Options

Medicare, the federal health insurance program for Americans age 65 and older and for certain individuals with disabilities, as well as individuals with end-stage renal disease, consists of four parts, Parts A through D. Almost all adults age 65 and older are automatically enrolled as beneficiaries in Part A, which covers inpatient services in hospitals and hospices, related posthospital care in skilled nursing facilities, and home health services.[15] Medicare beneficiaries have the option to enroll in Part B, which covers physician, outpatient, and some preventive services. Part C, also known as the Medicare Advantage program, allows beneficiaries who are eligible for benefits under Part A and Part B to enroll in a private plan, such as a health maintenance organization, preferred provider organization, or private fee-for-service plan, as an alternative to the traditional Part A and Part B programs. Finally, Part D is Medicare's optional outpatient prescription drug benefit program.

In 2009, nearly 38 million beneficiaries age 65 and older were enrolled in Part A,[16] and about 22 million (58 percent) of those were enrolled in

[15]Individuals age 65 and older are automatically enrolled in Part A if they are U.S. citizens or permanent legal residents and if they or their spouses are eligible for Social Security payments and have made payroll tax contributions for 10 or more years. Those individuals age 65 and older who are not automatically enrolled may purchase Part A coverage. In this report, we use the term Medicare beneficiaries to refer to those individuals age 65 and older enrolled in Part A, and we consider Part A enrollment as the total Medicare enrollment. CMS reports that in 2010, less than 1 percent of Medicare beneficiaries were enrolled in Part B, but not in Part A. Beneficiaries must be enrolled in Part A or Part B to enroll in Part D.

[16]An additional 7.5 million disabled individuals under age 65 were enrolled in Medicare Part A in 2009.

Part D (see table 1).[17] Approximately 9.8 million beneficiaries elected to receive their Part A and Part B benefits through Part C Medicare Advantage plans.

Table 1: Medicare Enrollment, Age 65 and Older, 2009

Medicare coverage	Eligibility	Enrollment (in millions)
Part A – hospital insurance	Automatic	37.8
Part B – physician and outpatient insurance	Optional	35.6
Part C – Medicare Advantage (alternative to Parts A and B)	Optional	9.8
Part D – prescription drug coverage	Optional	21.8

Source: GAO analysis of CMS 2009 Data Compendium.

Part A typically has no premiums but includes deductibles and co-payments, whereas the optional Parts B, C, and D typically require that beneficiaries pay premiums and share costs, including deductibles, co-payments, or coinsurance.[18] For most physician and outpatient services covered under Part B, beneficiaries typically pay 20 percent of the Medicare-approved amount; however, no cost sharing is required for certain preventive services covered under Part B.[19] For beneficiaries in Part C Medicare Advantage plans, beneficiary cost sharing may vary. All Medicare beneficiaries may elect to enroll in Part D. Medicare beneficiaries obtain Part D coverage by choosing from multiple competing

[17]According to the Medicare Payment Advisory Commission (MedPAC), in 2009 most Medicare beneficiaries who did not elect Part D coverage had alternate drug coverage—such as employer-sponsored coverage or coverage through other federal programs—that was at least equal to Part D's defined standard benefit. See MedPAC, *Report to the Congress: Medicare Payment Policy* (Washington, D.C.: Mar. 2010), 286, accessed August 18, 2011, http://www.medpac.gov/documents/Mar10_EntireReport.pdf.

[18]A deductible is an amount a beneficiary pays before Medicare will begin to pay—the Part A deductible for 2011 is $1,132, and the Part B deductible is $162. See CMS, *Medicare and You* (Baltimore, Md.: Feb. 2011), accessed August 8, 2011, http://www.medicare.gov/publications/pubs/pdf/10050.pdf. A co-payment is usually a fixed amount paid by the beneficiary, such as $20 for an office visit, whereas coinsurance is a percentage of the item's or service's cost.

[19]PPACA requires that Medicare Part B cover 100 percent of the charge for services recommended with a grade of A or B by the U.S. Preventive Services Task Force. Pub. L. No. 111-148, §§ 4104, 10406, 124 Stat. 557, 975 (amending the Social Security Act (SSA) § 1833(a)(1)).

Part D prescription drug plans offered by plan sponsors—often private insurers—that contract with CMS to offer the outpatient prescription drug benefit. Part C Medicare Advantage plans may also sponsor Part D prescription drug plans that offer outpatient prescription drug coverage to their members. Of the nearly 22 million beneficiaries enrolled in Part D prescription drug plans in 2009, about 30 percent were enrolled in Medicare Advantage prescription drug plans.

At a minimum, Part D plans must offer a standard benefit established under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)[20] or an actuarially equivalent plan. The standard benefit has an annual deductible, and includes coverage up to a specified level of spending, a coverage gap—the so-called donut hole—when beneficiaries pay a greater portion of the cost of their drugs, and catastrophic coverage above a specified cost-sharing limit.[21] Plan sponsors can offer a range of Part D plans that vary in the coverage provided, monthly premiums, and cost-sharing arrangements, such as deductibles and co-payments.

To help defray out-of-pocket prescription drug costs for low-income Medicare beneficiaries, Part D offers a low-income subsidy (LIS) for eligible beneficiaries.[22] LIS beneficiaries get help paying for their premiums and deductibles and generally have zero or nominal cost

[20]Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2071-2152 (adding a new Part D to title XVIII of the SSA, which establishes a voluntary Medicare prescription drug benefit program, including SSA § 1860D-2, which contains prescription drug benefit requirements).

[21]Starting on January 1, 2011, a provision in PPACA reduced Part D beneficiaries' cost sharing in the coverage gap, or donut hole, by 50 percent for applicable drugs and phases out the donut hole by 2020, at which time Part D beneficiaries' cost sharing will be 25 percent until beneficiaries' Part D drug costs reach the catastrophic threshold. See Pub. L. No. 111-148, § 3301, 124 Stat. 461 (as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 1101, 124 Stat 1029, 1036).

[22]Pub. L. No. 108-173, § 101, 117 Stat. 2071-2152 (adding SSA § 1860D-14, which establishes premium and cost-sharing subsidies for low-income individuals). Under the Part D drug program, coverage for all Medicare beneficiaries is subsidized; however, LIS beneficiaries receive additional subsidy support.

sharing and no coverage gap. In 2009, about 30 percent of Part D beneficiaries age 65 and older received the LIS.[23]

Medicare Coverage of Routinely Recommended Adult Vaccinations

Medicare coverage of vaccinations routinely recommended by ACIP for adults age 65 and older is divided between Part B and Part D (see table 2), and ACIP reviews its recommendations annually.[24] As of August 2011, Part B covered the influenza and pneumococcal vaccines at no cost to the beneficiary, even though Part B beneficiaries typically pay 20 percent of the Medicare-approved amount for most physician and outpatient services covered under Part B. Vaccinations administered to treat an injury or exposure to a disease—but not as routinely recommended preventive measures—such as a Td/Tdap vaccination following possible exposure to tetanus from stepping on a rusty nail, are also covered under Part B.[25] As of August 2011, Td vaccinations that are recommended as a booster every 10 years and Tdap vaccinations that are recommended as a onetime replacement for one of the boosters, to prevent the diseases, are covered under Part D.[26] Part D coverage encompasses all vaccinations not specifically covered by Part B,

[23]The Part D population eligible for the LIS may be substantially greater. For example, according to a September 2010 report by the Henry J. Kaiser Family Foundation, more than 2 million Medicare beneficiaries were eligible for the LIS in 2009 but did not receive it. Most LIS beneficiaries received the full LIS, thus paying no premiums or deductibles as long as they enrolled in so-called "benchmark" stand-alone prescription drug plans. Benchmark plans are those plans with premiums at or below a specified benchmark for a given geographic region, as calculated by CMS. Full LIS beneficiaries may enroll in other Part D plans but must pay any difference between the premium of the plan in which they choose to enroll and the benchmark for their region.

[24]For additional information on the schedule of adult vaccinations approved by ACIP for 2011, see CDC, "Recommended Adult Immunization Schedule—United States, 2011," *Morbidity and Mortality Weekly Report*, vol. 60, no.4 (2011), accessed February 22, 2011, http://www.cdc.gov/vaccines/recs/schedules/downloads/adult/mmwr-adult-schedule.pdf.

[25]The hepatitis B vaccination is covered under Part B for beneficiaries at high or intermediate risk of contracting the disease based on certain behavioral and health factors, including residing in an institution for people with developmental disabilities, using injection drugs, receiving hemodialysis, or having end-stage renal disease.

[26]In October 2010, ACIP revised its recommendation for Tdap. Adults age 65 years and older who have not previously received Tdap and who have close contact with an infant less than 12 months old should be vaccinated with Tdap, rather than Td, and other adults age 65 years and older may receive Tdap. Tdap can be administered regardless of the interval since the most recent Td/Tdap vaccination. In 2011, the Food and Drug Administration expanded the age indication for one Tdap vaccine for adults age 65 years and older.

including the shingles vaccination, which since 2006 has been recommended for all adults age 60 and older (except for adults with certain symptoms or conditions, such as the human immunodeficiency virus).[27] (See app. II for more information on shingles.) Unlike Part B, Part D plans vary in their cost-sharing arrangements, including cost sharing for vaccinations. For beneficiaries in the coverage gap in 2009, cost sharing could be up to 100 percent of the vaccination cost. All other vaccinations covered under Part D in 2011 were either not routinely recommended for adults age 65 and older or were recommended only in cases where certain risk factors were present.

Table 2: Medicare Coverage of ACIP's Routinely Recommended Preventive Vaccinations for Adults Age 65 and Older, February 2011

	Medicare coverage		
Vaccine	**Part B**	**Part D**	**Recommendation**
Influenza	√		Annually
Pneumococcal	√		Once age 65 and older
Td[a]		√	One booster every 10 years
Shingles[b]		√	Once age 60 and older

Source: GAO analysis of Medicare coverage and ACIP recommendations as of February 2011.

Notes: We did not include as "routinely recommended" the vaccinations that ACIP recommended only for individuals age 65 and older with certain risk factors, such as vaccinations to prevent measles, mumps, and rubella; hepatitis A; hepatitis B; and meningitis. In addition, although ACIP recommended the varicella (chicken pox) vaccination for all adults without evidence of immunity to chicken pox, being U.S.-born prior to 1980 is considered to be evidence of immunity. ACIP also recommended specific vaccinations for individuals traveling to some foreign countries.

[a]In 2010, ACIP recommended a onetime Tdap vaccination as a replacement for one Td booster for adults age 65 and older. Part B covers the Td or Tdap vaccination when it is related to the treatment of an injury or incidence of exposure; Part D covers the routinely recommended Td or Tdap vaccination when administered as a booster to prevent the diseases.

[b]ACIP added the recommendation for the shingles vaccination for adults age 60 and older in 2006.

Under Part D, physicians' and pharmacies' status as "in-network" or "out-of-network" providers affects their ability to verify beneficiary coverage and bill Part D plans. Beneficiaries may receive their Medicare Part B- or Part D-covered vaccinations from a physician or a pharmacy. Part B-covered vaccinations—including those for influenza, pneumonia, and

[27]As new adult vaccines are developed, licensed, and routinely recommended for Medicare beneficiaries, they will be covered under Part D unless coverage is specifically required under Part B.

hepatitis B for certain individuals—have been traditionally provided in physicians' offices. However, pharmacies are playing an increasing role in providing adult vaccinations and can submit Part B claims to Medicare for Part B-covered vaccinations—as, for example, when a pharmacy offers annual influenza vaccinations. Part D is organized through networks of pharmacies under contract with prescription drug plans. As in-network providers, pharmacies typically have access to online, real-time systems to verify beneficiaries' Part D vaccination coverage, determine the required Part D cost-sharing amount, and bill Part D plans. However, under Part D, physician offices are typically considered out-of-network providers and generally do not have the same type of online, real-time systems pharmacies have to verify coverage, determine the beneficiary cost-sharing amount, and obtain Part D reimbursement.

About One-Tenth of Medicare Beneficiaries Have Received Shingles Vaccinations, about Half Have Received Td Vaccinations, and Relatively Few Received Them under Part D

National survey data from 2009 indicate that about one-tenth of the nearly 38 million Medicare beneficiaries have received the routinely recommended onetime shingles vaccination and about half are up-to-date with their Td vaccinations. The survey data also show that Medicare beneficiaries with both Part D and other insurance coverage reported receiving shingles and Td vaccinations at similar percentages as beneficiaries with other types of coverage. Medicare Part D data for 2007 through 2009 indicate that relatively few Part D beneficiaries received shingles and Td vaccinations under Part D. These data suggest that some Medicare beneficiaries received their vaccinations outside of Part D, either prior to enrolling, using other health coverage, or paying out of pocket.

NHIS Data Indicate That 11 Percent of Medicare Beneficiaries Have Received a Shingles Vaccination and 53 Percent Have Received a Td Vaccination

NHIS data from 2009 indicate that 11 percent of Medicare beneficiaries[28] reported ever receiving a shingles vaccination[29] and 53 percent reported receiving a Td vaccination in the previous 10 years—the time interval recommended between boosters. The shingles vaccine has been available since 2006, and the percentage of adults age 65 and older reporting ever receiving this vaccination has increased since 2007 (see table 3). Using the 2008 NHIS data as a baseline, HHS set a national target for the percentage of adults age 60 and older who report ever receiving the shingles vaccination of 30 percent by 2020.[30]

[28]We analyzed NHIS data for adults age 65 and older because this age group closely corresponds to the Medicare population.

[29]While ACIP recommends that most people age 60 and older should receive a shingles vaccination, the vaccine is contraindicated for some of them, meaning they may have symptoms or conditions that would make the vaccination inadvisable. Contraindications for the shingles vaccination include certain immunocompromising conditions such as infection with the human immunodeficiency virus. Using Medicare data, we estimated that from 2 to 6 percent of Medicare beneficiaries age 65 and older had at least one immunocompromising condition that could contraindicate the shingles vaccine from 2007 through 2009.

[30]In December 2010, HHS announced its targets for Healthy People 2020, the nation's 10-year goals and objectives for health promotion and disease prevention. Healthy People 2020 includes objectives with target rates for vaccination against specific diseases for different age groups. The target of 30 percent for shingles vaccination was established using 2008 NHIS data as a baseline, and progress toward the objective to increase the percentage of adults who are vaccinated against shingles will be measured using NHIS data. According to HHS, the shingles vaccination target was set in view of the many external barriers, including supply constraints. The 2008 NHIS data showed that 7 percent of adults age 60 and older reported having ever received a shingles vaccination. Healthy People does not have a 2020 target for Td vaccination. See http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=23 (accessed Sept. 6, 2011).

Table 3: Percentage of Adults Age 65 and Older Reporting Ever Receiving Shingles Vaccination or Receiving Td Vaccination in Previous 10 Years, 2007 through 2009

Vaccination	2007	2008	2009
Shingles[a]	2.3	7.6	11.0
Td[b]	44.1	51.9	52.8

Source: GAO analysis of CDC National Immunization Survey (2007) and NHIS (2008 and 2009).

Note: The age 65 and older population surveyed closely corresponds to the Medicare population.

[a]National estimates of the percentage of adults age 65 and older who reported ever receiving a shingles vaccination.

[b]National estimates of the percentage of adults age 65 and older who reported receiving a Td vaccination in the previous 10 years. Data include Td vaccinations administered as a treatment or as a preventive measure.

NHIS data can also provide national estimates of adults who reported receiving shingles or Td vaccinations based on type of insurance coverage. NHIS data indicate that Medicare beneficiaries with both Part D and other insurance coverage reported receiving shingles or Td vaccinations at similar percentages as beneficiaries with other types of coverage (see table 4). (See app. III for additional NHIS data on shingles and Td vaccination by selected demographic groups.)

Table 4: Percentage of Adults Age 65 and Older Reporting Ever Receiving Shingles Vaccination or Receiving Td Vaccination in Previous 10 Years, by Insurance Coverage, 2009

		Without Part D coverage		With Part D coverage	
Vaccination	All respondents	No other coverage[a]	With private or other coverage[a]	No other coverage	With private or other coverage[a]
Shingles[b]	11.0	10.7	13.4	11.5	14.6
Td[c]	52.8	52.8	54.8	52.6	56.0

Source: GAO analysis of CDC NHIS (2009).

Note: The age 65 and older population surveyed closely corresponds to the Medicare population.

[a]Other coverage includes Medicaid, a state-sponsored or other government-sponsored health plan, or a military plan.

[b]National estimates of the percentage of adults age 65 and older who reported ever receiving a shingles vaccination.

[c]National estimates of the percentage of adults age 65 and older who reported receiving a Td vaccination in the previous 10 years. Data include Td vaccinations administered as a treatment or as a preventive measure.

National survey data also show that some individuals obtain shingles or Td vaccinations prior to age 65, the typical enrollment age for Medicare. NHIS data for 2009 show that almost 8 percent of adults age 60 to 64 reported that they had received the onetime shingles vaccination. For Td, the reported coverage rate is even higher—NHIS data for 2009 show that almost 60 percent of adults age 60 to 64 reported being up-to-date with their Td vaccinations.

Medicare Data for 2007 through 2009 Indicate That Relatively Few Beneficiaries Received Shingles and Td/Tdap Vaccinations under Part D

Medicare Part D data for 2007 through 2009 indicate that relatively few Part D beneficiaries received shingles and Td/Tdap vaccinations under Part D.[31] Specifically, the data show that Part D plans reimbursed shingles vaccinations for about 5 percent of Part D beneficiaries and Td/Tdap vaccinations for less than 1 percent of Part D beneficiaries.[32] Few beneficiaries had other vaccinations reimbursed through Part D, as shingles vaccinations accounted for 89 percent of all Part D-reimbursed vaccinations, and Td/Tdap vaccinations accounted for 10 percent of Part D-reimbursed vaccinations during this period.[33]

Part D data also show that the percentages of beneficiaries with vaccinations reimbursed by Part D varied slightly among different groups of beneficiaries, specifically, between those in Medicare Advantage prescription drug plans and those in other Part D prescription drug plans and between LIS and non-LIS beneficiaries. For example, in 2009, about 30 percent of Part D beneficiaries were in Medicare Advantage prescription drug plans, and a slightly higher percentage of these beneficiaries had shingles and Td/Tdap vaccinations reimbursed by Part D plans than beneficiaries in other Part D prescription drug plans (see table 5). LIS beneficiaries—who make up approximately 30 percent of Part D beneficiaries—had Part D reimburse for shingles and Td/Tdap vaccinations less frequently than those Part D beneficiaries who did not

[31]To determine the percentage of Part D beneficiaries reimbursed for vaccinations that protect against tetanus and diphtheria, both with and without the pertussis component, we examined Part D data for both Td and Tdap.

[32]These reimbursement figures include beneficiaries in the donut hole.

[33]The other vaccinations reimbursed under Part D include those for hepatitis A; hepatitis B for individuals at low risk for contracting the disease; and travel-related illnesses, such as yellow fever.

receive the subsidy. (See app. III for additional Part D data on vaccination by selected demographic groups.)

Table 5: Vaccinations Reimbursed by Part D for Medicare Beneficiaries, by Part D Plan Type and LIS Status, 2007 through 2009

		Percentage of Part D beneficiaries with shingles vaccinations under Part D	Percentage of Part D beneficiaries with Td/Tdap vaccinations under Part D[a]
All beneficiaries		4.59	0.49
By plan type	Medicare Advantage prescription drug plans	5.33	1.44
	Other Part D prescription drug plans	4.27	0.09
By LIS status	Non-LIS	5.93	0.63
	LIS	1.87	0.21

Source: GAO analysis of 2007 through 2009 Medicare Part D data.

Note: We analyzed Part D data for beneficiaries age 65 and older enrolled in a Part D plan at any time from 2007 through 2009, excluding those enrolled in employer plans, religious fraternal benefit plans, CMS demonstrations, and programs of all-inclusive care for the elderly.

[a]To determine the percentage of Part D beneficiaries reimbursed for vaccinations that protect against tetanus and diphtheria, both with and without the pertussis component, we examined Part D data for both Td and Tdap.

In addition to their Medicare coverage, beneficiaries may have other coverage that could help pay for routinely recommended vaccinations. The Medicare Payment Advisory Commission (MedPAC) reported that in 2009, 90 percent of Medicare beneficiaries had drug coverage, including employer-based or other federal coverage, that was at least as generous as Part D's defined standard benefit, which covers routinely recommended vaccinations not covered by Part B.[34]

[34]MedPAC, *Report to the Congress: Medicare Payment Policy*.

A Multitude of Factors Affect Beneficiaries' Access to Part D-Covered Vaccinations, Particularly for Shingles

On the basis of our physician, pharmacy, and SHIP surveys, we identified a multitude of factors that affect Part D beneficiaries' access to routinely recommended Part D-covered vaccinations. Most physicians do not stock the shingles vaccine due to factors such as the cost of purchasing a supply of the vaccine and administrative challenges related to reimbursement. In comparison with other vaccinations, physicians recommend shingles vaccinations less frequently, and even when a shingles vaccination is recommended by a physician, beneficiaries may decide not to get it. Additionally, most pharmacies do not stock either the shingles or the Td/Tdap vaccines. Finally, some beneficiaries may find it difficult to afford the cost-sharing requirements or, if their physicians do not bill Part D plans, to pay the full cost up front for Part D vaccinations.

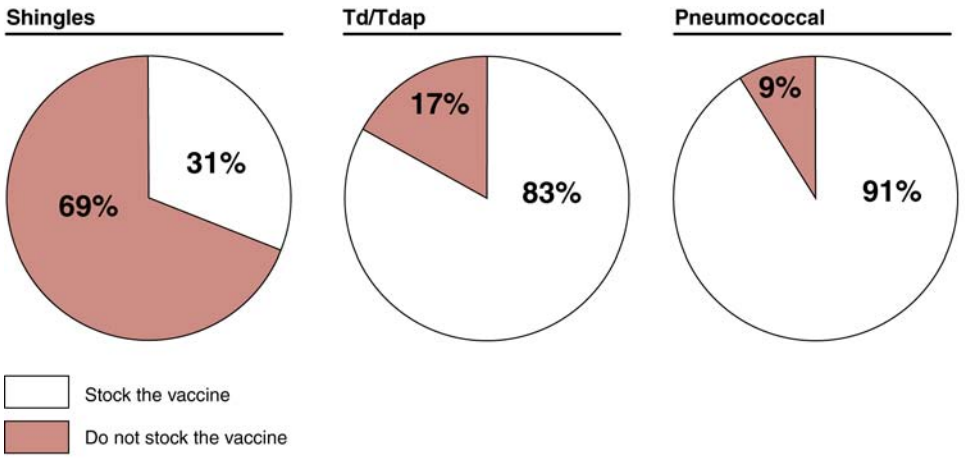
Most Physicians Do Not Stock the Shingles Vaccine, in Contrast to Other Vaccines, Due to Cost and Part D Administrative Challenges

Based on our 2010 survey of physicians, we estimate that nearly 7 in 10 primary care physicians—the primary providers of preventive services to Medicare beneficiaries—do not stock the Part D-covered shingles vaccine.[35] (See fig. 1.) In contrast, we estimate that about 2 in 10 physicians do not stock Td/Tdap vaccines, and about 1 in 10 does not stock the Part B-covered pneumococcal vaccine.[36]

[35]To allow us to project to the national level, all statistics from our physician survey are weighted estimates. All percentage estimates from the survey have a margin of error at the 95 percent confidence level of plus or minus 8 percentage points or less, unless otherwise noted. In addition, our physician survey assumed that physicians who stock vaccines also administer them.

[36]We surveyed providers on their common practices for the Part B-covered pneumococcal vaccine as a comparison for their practices for the Part D-covered shingles and Td/Tdap vaccines. Similar to the shingles vaccination, the pneumococcal vaccination is generally a single-dose vaccination recommended for older adults.

Figure 1: Physicians Stocking the Shingles, Td/Tdap, and Pneumococcal Vaccines



Source: GAO 2010 Physician Survey.

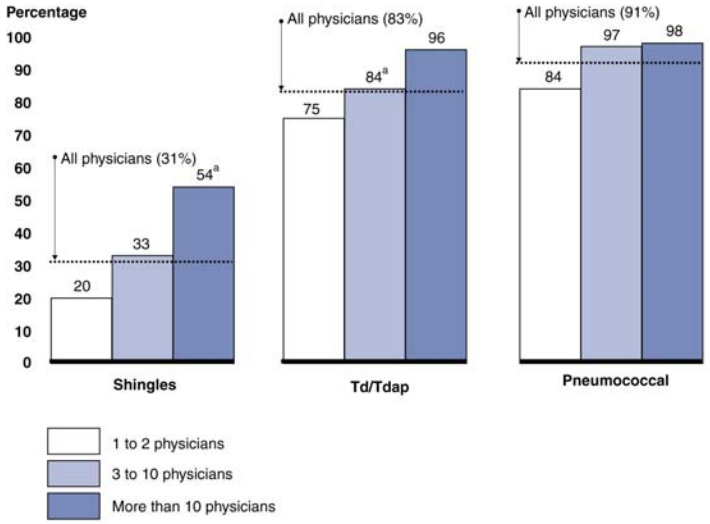
Note: The sampling frame for our survey included practicing family and internal medicine physicians in the United States who were not federal employees and who provided primary care to Medicare beneficiaries age 65 and older.

One factor that is related to whether a physician stocks the shingles vaccine is the size of the physician's practice. Our 2010 survey of physicians found that smaller practices stock the shingles vaccine less frequently than larger practices. (See fig. 2.) Smaller practices with one or two physicians serve as the setting for nearly half of primary care physicians, according to 2005-2006 data from CDC,[37] and these practices are more frequently composed of a larger proportion of beneficiaries age 65 and older than larger practices, according to our survey. Thirty-seven percent of smaller practices had Medicare beneficiaries age 65 and older making up more than half of their patients, compared to 26 percent of practices with 3 to 10 physicians, and 21 percent of practices with more than 10 physicians.[38] Thus the practices that are more likely to have a higher proportion of Medicare beneficiaries may be less likely to stock the shingles vaccine.

[37]E. Hing and C.W. Burt, "Characteristics of Office-Based Physicians and Their Medical Practices: United States, 2005-2006," National Center for Health Statistics. *Vital and Health Statistics*, series 13, no. 166 (2008).

[38]The estimates for 1- or 2-physician and 3- to 10-physician practices have a margin of error above plus or minus 8 percentage points at the 95 percent confidence level.

Figure 2: Physicians Stocking the Shingles, Td/Tdap, and Pneumococcal Vaccines, by Practice Size



Source: GAO 2010 Physician Survey.

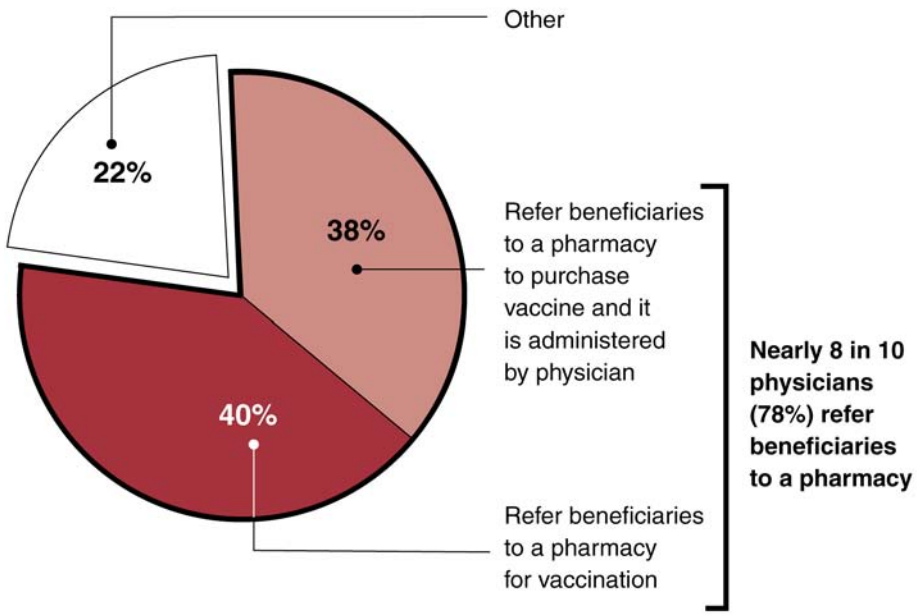
Note: The sampling frame for our survey included practicing family and internal medicine physicians in the United States who were not federal employees and who provided primary care to Medicare beneficiaries age 65 and older.

[a]Estimate has a margin of error above plus or minus 8 percentage points at the 95 percent confidence level.

Our survey also found that most physicians who do not stock the shingles vaccine themselves rely on pharmacies to stock it. As shown in figure 3, nearly 8 in 10 physicians who do not stock the shingles vaccine refer beneficiaries to a pharmacy to purchase it. Nearly half of those physicians administer the purchased shingles vaccine in their offices.[39]

[39]Our survey did not collect data on how the vaccine was transported from the pharmacy to the physician's office for administration, and some methods of transporting the shingles vaccine are preferable to others. For example, pharmacies may ship or transport the vaccine to the physician's office, with attention to proper storage and handling. In other cases, however, beneficiaries may purchase the vaccine at a pharmacy and transport the vaccine to their physician's office themselves—a practice called brown-bagging. Brown-bagging of shingles vaccine is considered unacceptable by CDC because the vaccine's efficacy—its ability to provide a certain degree of protection—can be compromised if it is not kept frozen prior to administration.

Figure 3: Referral Practices of Physicians Who Do Not Stock the Shingles Vaccine



Source: GAO 2010 Physician Survey.

Notes: Other includes physicians who refer beneficiaries to another physician or to a public health department for vaccination or who provided a different response.

The sampling frame for our survey included practicing family and internal medicine physicians in the United States who were not federal employees and who provided primary care to Medicare beneficiaries age 65 and older.

Physicians who do not stock the shingles vaccine cited a multitude of factors as barriers to stocking, administering, or recommending the vaccine.[40] (See table 6.) Our survey also found that most physicians (82 percent) identified more than one factor as a major barrier. The cumulative effect of these barriers may deter physicians from stocking the vaccine.

[40]Physician respondents were asked to classify 14 listed factors as a major barrier, a minor barrier, or not a barrier to stocking, administering, or recommending the shingles vaccine. The discussion here centers on the responses of physicians who do not stock the vaccine; for survey results for physicians who do stock the vaccine, see app. IV.

Table 6: Barriers Cited by Physicians Who Do Not Stock the Shingles Vaccine

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Inconsistent Part D plans' coverage and reimbursement rates	94 (92, 96)	76 (71, 82)	18 (13, 22)
Cost of purchasing vaccine stock	90 (88, 93)	79 (75, 83)	11 (7, 16)
Low Medicare reimbursement for the cost and/or administration of the vaccine	90 (86, 94)	70 (66, 74)	20 (15, 24)
The time and effort required to assess beneficiary Medicare coverage for the vaccine and pursue Medicare reimbursement for providing and/or administering the vaccine	86 (84, 88)	65 (59, 70)	22 (17, 26)
Beneficiaries' difficulty affording the cost sharing for the vaccine	85 (80, 90)	66 (59, 72)	19 (15, 24)
Beneficiaries' lack of insurance coverage	83 (78, 88)	59 (53, 64)	24 (20, 28)
Lack of, or uncertain, beneficiary demand for the vaccine	58 (53, 63)	21 (16, 26)	37 (32, 42)
The need for beneficiaries to transport the vaccine from a pharmacy to a physician to be administered	58 (52, 64)	27 (23, 31)	31 (26, 35)
Trouble stocking the vaccine due to shortage/order backlog	56 (50, 62)	30 (26, 34)	26 (21, 31)
Beneficiaries' concern about vaccine's safety	47 (41, 54)	10 (6, 14)	37 (31, 43)
Beneficiaries' concern about vaccine's efficacy	46 (40, 52)	10 (5, 15)	36 (31, 42)
Storage difficulties (the need to store the vaccine in a refrigerator/freezer)	41 (37, 46)	23 (20, 26)	18 (13, 23)
Physician's concern about vaccine's efficacy	30 (25, 35)	8 (5, 12)	22 (17, 26)
Physician's concern about vaccine's safety	18 (13, 24)	3 (2, 4)	15 (10, 20)

Source: GAO 2010 Physician Survey.

Notes: Respondents were asked to classify the 14 listed factors as a major barrier, a minor barrier, or not a barrier to stocking, administering, or recommending the shingles vaccine.

The sampling frame for our survey included practicing family and internal medicine physicians in the United States who were not federal employees and who provided primary care to Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

The sum of the percentages of major and minor barriers may not equal the total percentage due to rounding.

Of the 14 factors that physicians could choose to cite as barriers on our survey, physicians who do not stock the shingles vaccine often cited reimbursement issues, the cost of purchasing a vaccine stock, and multiple administrative challenges related to Part D as barriers. About 9 in 10 physicians who do not stock the shingles vaccine cited inconsistent and low reimbursement rates and the cost of purchasing a stock of the vaccine as barriers. As of December 2009, the retail price of the shingles vaccine, which is the highest price per dose for a routinely recommended adult vaccine, was about $154 per dose when purchased in a 10-dose

Shingles Vaccine Supply

The sole manufacturer of the shingles vaccine for the U.S. market has reported that since the vaccine first came on the U.S. market in 2006, it has periodically experienced difficulty meeting demand, and the short supply has necessitated some back orders. The manufacturer, which also produces the chicken pox vaccine, has cited multiple reasons for the limited supply. For example, the shingles vaccine contains the same key ingredient as the chicken pox vaccine, which is routinely recommended for children, and in 2006 ACIP changed the recommendation for the chicken pox vaccine from one dose to two. In response, the shingles vaccine manufacturer assigned a higher priority to the production of the chicken pox vaccine, which contributed to the supply challenges for the shingles vaccine. The manufacturer has also reported delays in manufacturing caused by difficulties in production, although manufacturer officials expected an increase in production for 2011.

CDC officials told us that neither CDC nor the manufacturer has heavily promoted the shingles vaccine because of the limited supply, likely affecting beneficiaries' awareness of and demand for it. In addition, the manufacturer's ability to market a refrigerated formulation of the shingles vaccine has also been affected by the limited supply of a key ingredient. According to the manufacturer, a refrigerated formulation of the vaccine licensed in the United States was not being marketed as of June 2011 because it requires significantly more of the key ingredient than the frozen vaccine. The limited supply was also factored into ACIP's decision making for its shingles vaccination recommendation. The Food and Drug Administration approved the use of shingles vaccine for adults age 50 and older in March 2011. In June 2011, however, ACIP decided not to expand its recommendation to include adults age 50 to 59, in part because of inadequate vaccine supply.

The supply issues contribute to the challenges of identifying the barriers to shingles vaccinations. As a CDC shingles expert who participated in our IOM-facilitated panel discussion noted, it is very difficult to provide empirical data on the barriers to Part D vaccinations because they are so complex. The expert described the situation as a "witch's brew" of barriers to shingles vaccinations, including limited supply, administrative challenges, limited marketing of the vaccine, and insufficient education for providers and beneficiaries.

package, or $162 for a single dose.[41] Physicians who do not stock the vaccine also cited concerns about administrative challenges related to reimbursement. Because Part D reimbursement rates may vary based on beneficiaries' Part D plans, without real-time access to beneficiary coverage information, physicians may not know how much Part D plans will reimburse for shingles vaccinations. In addition, more than 8 in 10 physicians cited the amount of time and effort needed to identify beneficiaries' coverage and submit claims for reimbursements as a barrier.[42]

Other frequently cited barriers in our physician survey included those associated with beneficiaries' ability to pay for, and their demand for, shingles vaccinations. More than 8 in 10 physicians cited beneficiaries' difficulty affording the cost sharing and beneficiaries' lack of Part D coverage or other insurance as barriers. And nearly 6 in 10 physicians cited a lack of, or uncertain, beneficiary demand for shingles vaccinations as a barrier.

Less frequently cited barriers included logistical concerns. Limited supply of the shingles vaccine may have deterred physicians from trying to stock it. Nearly 6 in 10 physicians who do not stock the shingles vaccine cited trouble stocking the vaccine due to the limited supply and order backlogs as a barrier. In addition, unlike other routinely recommended adult vaccines, the shingles vaccine must remain frozen until just prior to administration, and not all physicians have appropriate equipment to stock frozen vaccines.[43] More than 4 in 10 physicians who do not stock the shingles vaccine cited storage difficulties as a barrier.

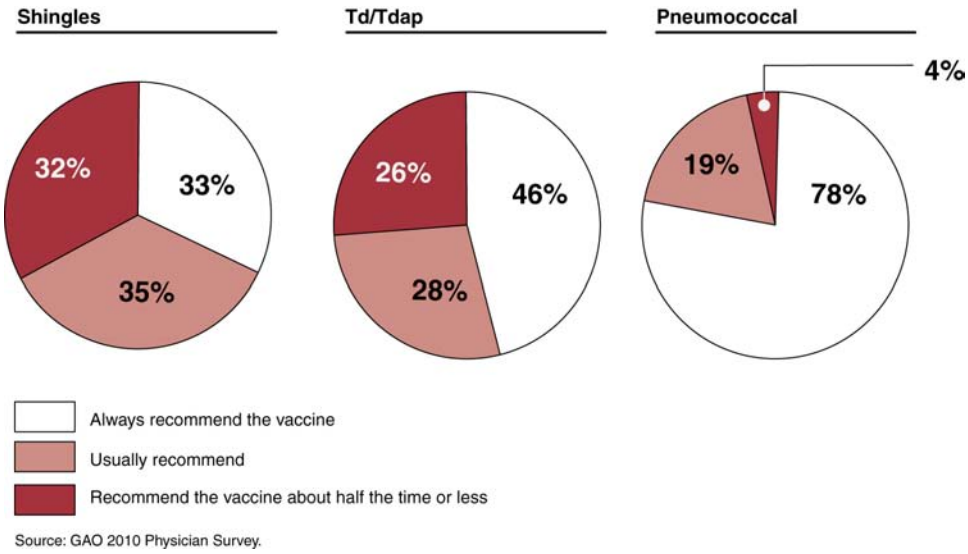
[41]These prices were reported by the shingles vaccine manufacturer to CDC.

[42]In our survey of physicians, we also asked physicians who provide care to Medicare beneficiaries at nursing facilities whether Medicare beneficiaries residing in nursing homes face any unique difficulties accessing Part D vaccinations. Physicians generally indicated that these beneficiaries do not, although some physicians noted that nursing homes generally do not stock shingles or Td/Tdap vaccines. Nursing home administrators told us that they generally do not stock shingles or Td/Tdap vaccines; instead, they order them when attending physicians recommend the vaccinations.

[43]The shingles vaccine is the only adult vaccine that must be stored frozen. To properly maintain a frozen supply of the vaccine, physicians must have a freezer that has a separate sealed freezer door and reliably maintains an average temperature of -15 degrees Celsius (+5 degrees Fahrenheit) or colder. The vaccine must be administered within 30 minutes of removal from the freezer.

In addition to stocking the shingles vaccine less frequently than other vaccines, physicians recommend shingles and Td/Tdap vaccinations to beneficiaries less frequently than the Part B-covered pneumococcal vaccination. (See fig. 4.) According to our survey, 2 in 3 physicians usually or always recommend the shingles vaccination, and 3 in 4 physicians usually or always recommend Td/Tdap vaccination. In comparison, nearly all physicians—more than 95 percent—usually or always recommend the pneumococcal vaccination.

Figure 4: Physician Recommendations for the Shingles, Td/Tdap, and Pneumococcal Vaccines



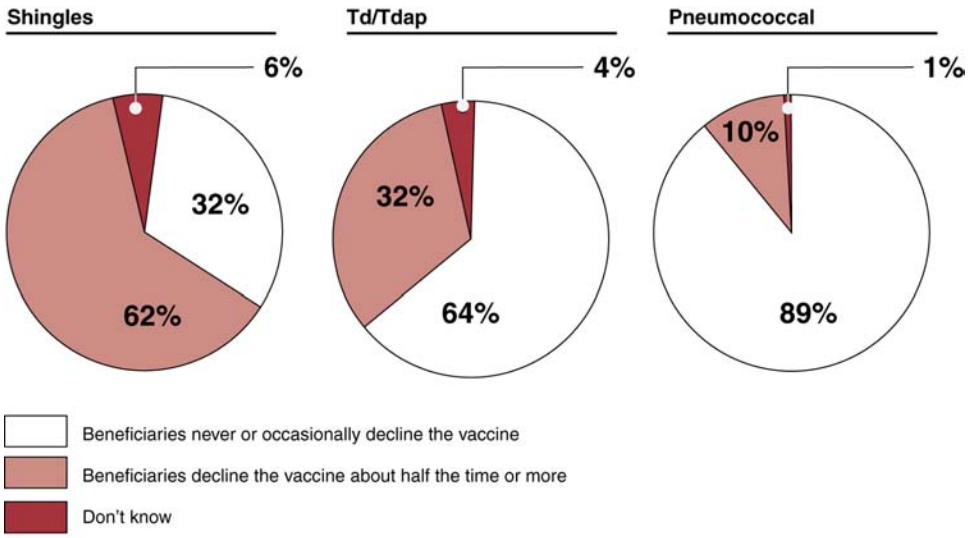
Source: GAO 2010 Physician Survey.

Notes: The sampling frame for our survey included practicing family and internal medicine physicians in the United States who were not federal employees and who provided primary care to Medicare beneficiaries age 65 and older.

Percentages may not total to 100 percent due to rounding.

Even when physicians recommend Part D-covered vaccinations, beneficiaries often decline them, particularly shingles vaccinations. According to our survey, after physicians recommend vaccinations, beneficiaries more frequently decline shingles vaccinations than Td/Tdap and pneumococcal vaccinations. More than 6 in 10 physicians report that beneficiaries decline shingles vaccinations about half the time or more. (See fig. 5.) In comparison, 1 in 10 physicians report that beneficiaries decline pneumococcal vaccinations half the time or more.

Figure 5: Beneficiary Declinations of Shingles, Td/Tdap, and Pneumococcal Vaccinations after Physicians Have Recommended Them



Source: GAO 2010 Physician Survey.

Notes: The sampling frame for our survey included practicing family and internal medicine physicians in the United States who were not federal employees and who provided primary care to Medicare beneficiaries age 65 and older.

Excludes physicians who never recommend shingles, Td/Tdap, or pneumococcal vaccinations. For each of the vaccinations, less than 2 percent of physicians never recommend the vaccination.

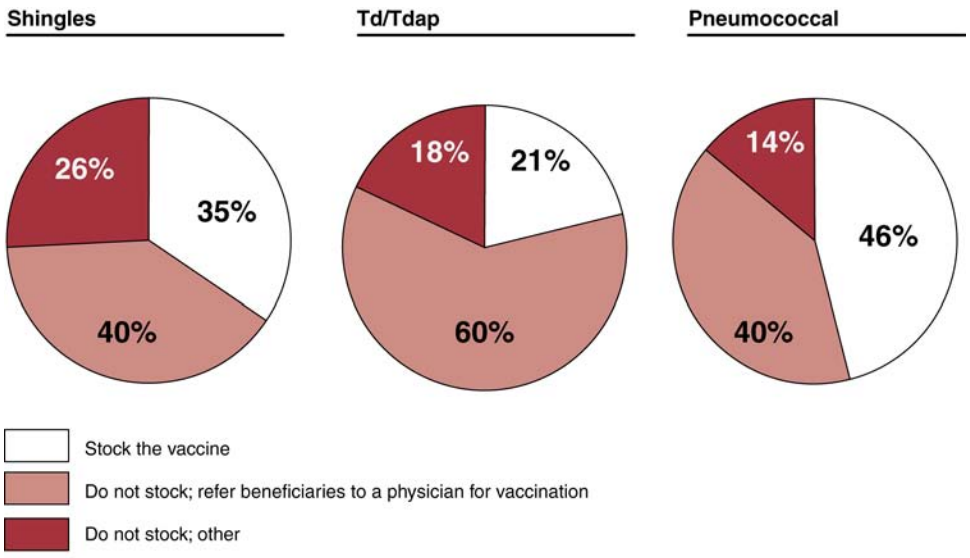
Most Pharmacies Do Not Stock Shingles or Td/Tdap Vaccines, and Many That Stock the Shingles Vaccine Face Limited Supply

Based on our 2010 survey of pharmacies, we estimate that nearly 7 in 10 pharmacies do not stock the shingles vaccine, nearly 8 in 10 do not stock Td/Tdap vaccines, and more than 5 in 10 do not stock the pneumococcal vaccine.[44] (See fig. 6.) Instead, pharmacies most commonly refer beneficiaries to physicians for their vaccinations. Although stakeholders told us that pharmacies are increasingly serving as an access point for Medicare beneficiaries' routinely recommended vaccinations, some pharmacies do not play an active role in providing the vaccines. Nearly 5

[44]To allow us to project to the national level, all statistics from our pharmacy survey are weighted estimates. All percentage estimates from the survey have a margin of error at the 95 percent confidence level of plus or minus 8 percentage points or less, unless otherwise noted.

in 10 pharmacies do not stock any of the three vaccines, and more than 3 in 10 do not regularly offer or recommend vaccinations to beneficiaries.[45]

Figure 6: Pharmacies Stocking the Shingles, Td/Tdap, and Pneumococcal Vaccines



Source: GAO 2010 Pharmacy Survey.

Notes: Other includes pharmacies that refer beneficiaries to other pharmacies or to a public health department for vaccination, or that provided a different response.

The sampling frame for our survey included pharmacies in the United States that were not operated by a federal agency and that served Medicare beneficiaries age 65 and older.

Percentages may not total to 100 percent due to rounding.

Moreover, not all pharmacies that stock vaccines administer them.[46] Based on our pharmacy survey, 2 in 10 pharmacies that stock the shingles vaccine and nearly 1 in 10 pharmacies that stock the Td/Tdap vaccines do not administer them.[47]

[45]Pharmacies were asked to classify the extent to which they offered and recommended routinely recommended vaccinations to beneficiaries, excluding influenza vaccinations.

[46]Unlike the physician survey, our pharmacy survey did not assume that any pharmacy that stocks a vaccine administers it.

[47]The estimate for the shingles vaccine has a margin of error above plus or minus 8 percentage points at the 95 percent confidence level.

Based on our pharmacy survey, pharmacies that do not stock the shingles vaccine cited a multitude of factors as barriers to stocking the vaccine. (See table 7.) Of the 15 factors that pharmacies could choose to cite as barriers, pharmacies that do not stock the shingles vaccine often cited beneficiaries' difficulty affording cost sharing and storage difficulties as barriers, with about 7 in 10 citing each as a barrier. In addition, more than 6 in 10 cited inconsistent Part D reimbursement rates as a barrier.

Table 7: Barriers Cited by Pharmacies That Do Not Stock the Shingles Vaccine

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Beneficiaries' difficulty affording the cost sharing for the vaccine	69 (64, 74)	33 (18, 48)	37 (22, 51)
Storage difficulties (the need to store the vaccine in a refrigerator/freezer)	69 (54, 83)	59 (39, 78)	10 (0, 23)
Inconsistent Part D plans' coverage and reimbursement rates	65 (61, 70)	45 (30, 60)	20 (6, 34)
Beneficiaries' lack of insurance coverage	59 (55, 62)	27 (13, 42)	31 (16, 46)
The time and effort required to assess beneficiary Medicare coverage for the vaccine and pursue Medicare reimbursement for providing and/or administering the vaccine	58 (44, 72)	45 (31, 58)	13 (9, 17)
Lack of, or uncertain, beneficiary demand for the vaccine	57 (38, 76)	33 (14, 52)	24 (20, 28)
The need for beneficiaries to transport the vaccine from a pharmacy to a physician to be administered	56 (42, 70)	37 (18, 56)	19 (6, 33)
Cost of purchasing vaccine stock	49 (30, 69)	25 (11, 39)	24 (12, 36)
Low Medicare reimbursement for the cost and/or administration of the vaccine	49 (30, 69)	21 (6, 35)	29 (16, 41)
Trouble stocking the vaccine due to shortage/order backlog	47 (27, 68)	39 (20, 58)	8 (5, 12)
Beneficiaries' concern about vaccine's efficacy	43 (29, 58)	9 (0, 24)	34 (16, 52)
Beneficiaries' concern about vaccine's safety	37 (22, 53)	10 (0, 26)	27 (8, 47)
State statutes/regulations do not allow pharmacist administration of the vaccine	19 (8, 31)	16 (6, 26)	3 (1, 6)
Pharmacy's concern about vaccine's safety	16 (4, 29)	2 (0, 4)	15 (3, 27)
Pharmacy's concern about vaccine's efficacy	16 (3, 28)	2 (0, 4)	14 (2, 25)

Source: GAO 2010 Pharmacy Survey.

Notes: Respondents were asked to classify the 15 listed factors as a major barrier, a minor barrier, or not a barrier to stocking, administering, or recommending the shingles vaccine.

The sampling frame for our survey included pharmacies in the United States that were not operated by a federal agency and that served Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

The sum of the percentages of major and minor barriers may not equal the total percentage due to rounding.

In addition, our pharmacy survey found that those pharmacies that do stock the shingles vaccine have faced difficulties obtaining the vaccine due to limited supply. For pharmacies that do stock the shingles vaccine, more than 8 in 10 cited trouble stocking the vaccine caused by vaccine shortages or order backlogs as a barrier.

Pharmacies that do not stock Td/Tdap vaccines also cited a number of factors as barriers to stocking the vaccine. Lack of beneficiary demand for the Td/Tdap vaccine and inconsistent Part D reimbursement rates were often cited as barriers.[48] (See table 8.)

Table 8: Barriers Cited by Pharmacies That Do Not Stock the Td/Tdap Vaccines

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Lack of, or uncertain, beneficiary demand for the vaccine	64 (49, 79)	40 (27, 53)	24 (15, 34)
Inconsistent Part D plans' coverage and reimbursement rates	62 (53, 71)	39 (32, 45)	24 (19, 28)
Beneficiaries' difficulty affording the cost sharing for the vaccine	58 (51, 65)	37 (27, 46)	21 (16, 27)
The time and effort required to assess beneficiary Medicare coverage for the vaccine and pursue Medicare reimbursement for providing and/or administering the vaccine	57 (49, 66)	36 (29, 43)	21 (17, 25)
Low Medicare reimbursement for the cost and/or administration of the vaccine	54 (45, 62)	22 (9, 36)	31 (18, 45)
Beneficiaries' lack of insurance coverage	51 (44, 58)	34 (23, 44)	17 (13, 21)
Trouble stocking the vaccine due to shortage/order backlog	42 (33, 51)	14 (1, 27)	28 (12, 44)
Storage difficulties (the need to store the vaccine in a refrigerator/freezer)	37 (30, 44)	17 (3, 31)	20 (7, 32)
Beneficiaries' concern about vaccine's efficacy	36 (20, 51)	12 (0, 25)	24 (11, 36)
Beneficiaries' concern about vaccine's safety	36 (19, 53)	13 (0, 26)	23 (9, 37)
State statutes/regulations do not allow pharmacist administration of the vaccine	30 (20, 40)	26 (16, 35)	5 (3, 7)
The need for beneficiaries to transport the vaccine from a pharmacy to a physician to be administered	28 (15, 40)	5 (0, 11)	22 (10, 35)
Cost of purchasing vaccine stock	25 (12, 38)	14 (2, 27)	11 (6, 15)
Pharmacy's concern about vaccine's safety	10 (7, 13)	2 (0, 4)	9 (7, 10)

[48]For additional pharmacy survey results, see app. V.

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Pharmacy's concern about vaccine's efficacy	10 (7, 13)	2 (0, 4)	8 (7, 10)

Source: GAO 2010 Pharmacy Survey.

Notes: Respondents were asked to classify the 15 listed factors as a major barrier, a minor barrier, or not a barrier to stocking, administering, or recommending the Td/Tdap vaccines.

The sampling frame for our survey included pharmacies in the United States that were not operated by a federal agency and that served Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

The sum of the percentages of major and minor barriers may not equal the total percentage due to rounding.

Beneficiaries Face Difficulties Accessing Part D Vaccinations, Particularly for Shingles, Due to Multiple Factors, Including Cost Concerns

According to our physician survey, Part D beneficiaries most commonly declined shingles vaccinations due to difficulties affording it. We estimate that about half of physicians who recommended a vaccination reported having had beneficiaries decline shingles vaccinations due to a lack of insurance coverage and about half had beneficiaries decline vaccinations due to difficulty affording cost sharing. Other reasons cited by physicians for beneficiaries declining the shingles vaccine include concerns about the vaccine's safety and efficacy and the need to obtain the vaccine outside of their physician's office (see app. IV for additional information from our physician survey).

Respondents to our SHIP survey reported that Part D beneficiaries faced a number of difficulties when seeking Part D-covered vaccinations. One of the primary roles of the SHIPs is to help beneficiaries understand their Medicare coverage. With Medicare coverage of vaccinations divided between Parts B and D, almost all SHIPs—47 of 51—reported helping beneficiaries understand whether a vaccination is covered under Part B or Part D, and 38 SHIPs reported helping beneficiaries understand their cost sharing for Part D-covered vaccinations, which can vary by plan (see app. VI for additional information from our SHIP survey).

SHIPs also reported that shingles vaccinations caused more difficulties for beneficiaries than did Td/Tdap or Part B-covered pneumococcal vaccinations.[49] (See table 9.) Beneficiaries' difficulty understanding

[49]SHIPs were given a list of potential beneficiary difficulties and were asked to select the ones where they had encountered beneficiaries experiencing difficulty. We also asked SHIPs whether Medicare beneficiaries under age 65 experienced any unique difficulties accessing Part D-covered vaccinations, and SHIPs generally indicated that they do not.

Medicare coverage and difficulty affording cost sharing and up-front costs were among the difficulties SHIPs reported more frequently for the shingles vaccination. Other difficulties reported by the SHIPs related to providers not stocking or administering the shingles vaccine, such as beneficiaries' concerns about having to transport the shingles vaccine from a pharmacy to their physician, and difficulties caused by their physician not stocking the vaccine or their pharmacy not administering the vaccine.

Table 9: Number of SHIPs Reporting Beneficiary Difficulties Accessing Shingles, Td/Tdap, and Pneumococcal Vaccinations

Beneficiary difficulties	Shingles	Td/Tdap	Pneumococcal
Do not know whether vaccination is covered by Medicare	36	16	20
Concerns about having to transport the vaccine from a pharmacy to a physician to be administered	24	3	1
Difficulty affording cost sharing for vaccination	20	2	N/A[a]
Physician does not stock the vaccine	19	0	2
Difficulty affording up-front costs of vaccination when responsible for pursuing reimbursement	18	2	3
Pharmacy does not administer the vaccine	17	1	4
Difficulty pursuing reimbursement for vaccination	14	3	4
Pharmacy does not stock the vaccine	10	3	2
Do not have Part D or other insurance coverage for vaccination	10	3	N/A[a]
Physician does not administer the vaccine	9	2	2

Source: GAO 2010 SHIP Survey.

Notes: SHIPs were given a list of potential beneficiary difficulties and were asked to select the ones where they had encountered beneficiaries experiencing difficulty.

All 51 SHIPs responded to the GAO survey.

[a]Nearly all Medicare beneficiaries have Part B coverage for pneumococcal vaccinations, which covers the vaccination with no beneficiary cost sharing.

Medicare data indicate that Part D cost sharing, particularly for the shingles vaccination, can be significant. Based on our analysis of Part D data, we found that in 2009, non-LIS Part D beneficiaries who had a shingles vaccination reimbursed by Part D were still responsible for cost sharing that averaged $57 for a shingles vaccination and $25 for a Td/Tdap vaccination, with cost sharing ranging as high as $195 for a

shingles vaccination.[50] (See table 10.) In contrast, beneficiaries have no cost sharing for pneumococcal vaccinations, which are covered under Part B (see app. VII for more information on beneficiaries' cost sharing for shingles and Td/Tdap vaccinations). The costs we found in our analysis are higher than those generally found to be acceptable to beneficiaries in a 2008 study of primary care physicians regarding shingles vaccination recommendations and barriers. That study reported that more than 7 in 10 physicians responded that their patients would be willing to spend no more than $29 in cost sharing for a shingles vaccination.[51]

Table 10: Cost Sharing and Retail Prices for the Shingles and Tetanus Vaccines, 2009

Vaccine	Average cost sharing[a]	Median cost sharing[a]	Range of cost sharing[a]	Approximate 2009 retail price[b]
Shingles	$57	$39	$0-$195	$154
Tetanus (Td/Tdap)[c]	$25	$27	$0-$70	$18 (Td) $37 (Tdap)

Source: GAO analysis of 2009 Medicare Part D data and CDC data.

Note: We analyzed Part D data for beneficiaries age 65 and older, excluding beneficiaries who received the LIS and those enrolled in employer plans, religious fraternal benefit plans, CMS demonstrations, and programs of all-inclusive care for the elderly.

[a]Cost-sharing amounts include payments for applicable vaccine administration fees.

[b]Retail prices presented are those reported by vaccine manufacturers to CDC and do not include vaccine administration costs.

[c]The average, median, and range of cost sharing for tetanus include both Td and Tdap vaccinations.

In addition to difficulty affording cost sharing, difficulty affording up-front payments can be a significant challenge to many beneficiaries. Because physicians are typically out of network for Part D vaccinations and do not have the real-time systems to verify coverage and bill Part D plans, beneficiaries may have to pay the full cost of their vaccination to the physician's office up front and obtain reimbursement from their Part D plans themselves. Our analysis of Part D data shows that in 2009, nearly

[50]Cost-sharing amounts include payments for applicable vaccine administration fees and apply to non-LIS beneficiaries age 65 and older. LIS beneficiaries generally have nominal cost sharing under Part D, including vaccines and administration fees. Prior to 2008, administration fees for Part D-covered vaccines were reimbursed by Part B.

[51]L.P. Hurley et al., "National Survey of Primary Care Physicians Regarding Herpes Zoster and the Herpes Zoster Vaccine," *Journal of Infectious Diseases*, vol. 197, supp. 2 (2008): S216-S223.

one in five shingles vaccination reimbursement requests (18 percent) and more than four in five Td/Tdap vaccination reimbursement requests (84 percent) were submitted by a beneficiary, indicating that Part D beneficiaries often paid up front for their vaccinations and obtained reimbursement themselves.[52] Beneficiaries who have to pay up front and obtain reimbursement from their Part D plans themselves may be less inclined to get vaccinated, and the up-front costs of a vaccination could be prohibitive for low-income Part D beneficiaries. Moreover, stakeholders, including Part D plan sponsors, told us that because Part D beneficiaries rarely submit Medicare reimbursements themselves, beneficiaries often encounter difficulties doing so.

Stakeholders' Recommendations to Improve Access to Part D Vaccinations Include Facilitating Payment to Physicians and Increasing Pharmacists' Authority to Administer Vaccinations

Many stakeholders have raised concerns about the administrative challenges associated with Medicare Part D and have recommended a range of actions to improve beneficiaries' access to Part D-covered vaccinations. Stakeholder recommendations, articulated at our IOM-facilitated discussion and conveyed in numerous correspondences and reports, include improving physicians' ability to verify coverage and bill Part D plans, consolidating Medicare coverage of vaccinations under Part B, and increasing pharmacists' authority to administer vaccinations in some states. CMS has issued some guidance on improving out-of-network billing for plans and providers, but participants at our IOM-facilitated discussion and other stakeholders report that administrative challenges persist and further action is needed. Consolidating Medicare coverage of all vaccinations under Medicare Part B has broad support among stakeholders, but it would require legislation and would likely increase federal Medicare costs. Finally, easing restrictions on pharmacists' authority to administer vaccinations could also increase access in states that currently impose limits, but would require state authorization.

[52]In contrast, less than 1 percent of all other Part D reimbursements were submitted by beneficiaries. In 2009, Part D reimbursements for the shingles and Td/Tdap vaccinations accounted for 0.07 percent of all reimbursements for beneficiaries age 65 and older.

Improving Physicians' Ability to Verify Coverage and Bill Part D Plans Could Help Improve Access

A number of stakeholders, including those representing physicians, report ongoing administrative challenges associated with Part D vaccinations and recommend improving physicians' ability to verify beneficiaries' Part D coverage and bill Part D plans to help improve access to routinely recommended vaccinations. CMS has issued some guidance to Part D plans and providers on options for facilitating out-of-network billing, such as a model vaccine notice that would provide plan-specific information on Part D coverage for physicians,[53] but participants at our IOM-facilitated discussion and other stakeholders report that further steps are needed. For example, one option identified, but not actively promoted, by CMS is to allow physicians to verify beneficiaries' Part D coverage and bill Part D plans for vaccinations in real time by using a web-based billing system. The American Medical Association, Part D plan sponsors, and others participating in our IOM-facilitated discussion have reported that such systems that allow physicians to submit claims to Part D plans could address some of the administrative challenges associated with Part D-covered vaccinations. However, as of July 2011, a single private company markets such a web-based system contracting with Part D plans for out-of-network reimbursements, and the system was not well known.[54]

The American Medical Association and others have reported that there is limited awareness among physicians of the web-based billing system, and that without such a system to facilitate vaccinations at the physician's office, patients may not get vaccinated at all. Further, the American Medical Association commented that efforts to increase awareness of the web-based billing system have been insufficient. We also found in our survey of physicians that nearly 3 in 4 physicians were not aware of any web-based billing systems that would allow them to electronically determine patient Part D coverage, submit claims for reimbursement for

[53]For example, see CMS, "Reimbursement for Vaccines and Vaccine Administration Under Medicare Part D;" *MLN Matters* (2007), accessed September 26, 2011, http://www.cms.gov/MLNMattersArticles/downloads/SE0727.pdf.

[54]Because Part D vaccination reimbursements are transactions with Part D plans, CMS does not provide physicians with access to such a web-based system. The private company that markets the system is TransactRx, which prior to 2010 was known as eDispense. We examined Part D data and found that in 2009, TransactRx processed about 10 percent of all Part D shingles vaccination reimbursements.

Part D vaccinations, or both.[55] In addition, participants at our IOM-facilitated discussion noted that physicians may be reluctant to install an additional billing system. They also noted that not all Part D plans participate in the web-based system. According to CMS, the web-based system could improve physicians' ability to bill Part D plans, but agency officials indicated that the agency would not promote this specific system because it was owned by a private company.

CMS has also provided limited guidance to Part D plans and providers regarding out-of-network billing options. The CMS guidance encourages Part D plans to offer beneficiaries vaccine-specific notices to take to their physician's office with instructions for the office on how to submit the out-of-network reimbursement for the beneficiary. CMS also informed physicians that they could coordinate with pharmacies to have them ship or deliver vaccines to physicians' offices, as well as coordinate with pharmacies to bill Part D plans for the vaccines. Beyond this guidance, a CMS official told us that the agency did not have plans to further facilitate physicians' ability to bill Part D plans and is limited in its ability to take action by the design of Part D. Despite these efforts, participants at our IOM-facilitated discussion in December 2010 noted that administrative challenges associated with Part D continue to hinder beneficiaries' access to vaccinations. In 2005, CMS acknowledged the potential for developing automatic crossover procedures to allow physicians to submit Part B claims for Part D-covered vaccinations that would be forwarded to the appropriate Part D plans.[56] More recently, CMS told us that Part B and Part D claim standards and systems are incompatible. While experience with Part D implementation may have brought to light technical difficulties inherent in coordinating these systems, it also demonstrated that some physicians have been able to submit and receive reimbursement for Part D claims using a web-based process. It is not clear that CMS has fully explored options for facilitating such a process for all physicians who seek to administer Part D-covered vaccinations.

[55]A survey administered by one of our IOM discussion participants found that in 2008, 93 percent of physicians were not aware of such a system. L.P. Hurley et al., "Barriers to the Use of Herpes Zoster Vaccine," *Annals of Internal Medicine*, vol. 152, no. 9 (2010): 555-560.

[56]*See* Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194, 4231, 4328 (Jan. 28, 2005) (discussion in preamble to final rule indicating that experience with Part D implementation will provide CMS with a better sense for the need and most appropriate mechanisms for such procedures).

Consolidating Vaccinations under Part B Has Broad Support but Would Require Legislation and Would Likely Increase Federal Costs

A range of stakeholders—including advisory groups; government agencies; and physician, pharmacy, and industry groups—have recommended consolidating Medicare coverage of all vaccinations under Medicare Part B. Stakeholders reported that consolidating vaccinations under Part B could address several administrative challenges associated with Part D—including challenges related to physicians' status as out-of-network providers, lack of beneficiary vaccine coverage, and beneficiary difficulty understanding Part D coverage. Many participants in our IOM-facilitated discussion—including officials from industry, professional organizations, and government agencies and researchers—recommended consolidating all vaccinations under Part B. As one participant noted, the complexity of the administrative processes associated with these vaccines creates challenges and adds cost. Providers do not know how much vaccine to stock, or how much they will be reimbursed once they deliver a vaccination. The more complex the process, the more staff time is needed to run the process. While participants cited a multitude of factors affecting beneficiary access to vaccinations covered under Part D, including difficulties storing the shingles vaccine and the limited supply of the vaccine, most participants identified administrative challenges associated with Part D as a primary concern. A CDC expert on shingles vaccination issues also stated that, without addressing this issue, the percentage of beneficiaries receiving the shingles vaccination would be limited.

The recommendation to cover all vaccinations under Part B raised by the IOM discussion participants is consistent with recommendations made by other stakeholders. Over 60 professional and advocacy organizations—including MedPAC, the National Vaccine Advisory Committee, and the American Medical Association—have made similar recommendations. In addition, 86 percent of physicians in our survey and the majority of the articles in our literature review recommended consolidating coverage of vaccinations under Part B.[57] Several provider professional organizations

[57]Of the 22 articles, letters, and policy statements in our literature review that made recommendations for improving access to Part D-covered vaccinations, 20 recommended covering all vaccinations under Part B. These articles cited many of the same concerns raised by the IOM-facilitated discussion participants, such as physicians' out-of-network status, and also provided support for the impact of these concerns, such as fewer physicians recommending Part D-covered vaccinations to their patients. Finally, our surveys found that 86 percent of physicians believe it would be easier for physicians to stock and administer routinely recommended vaccines if they were under Part B and 39 of 51 SHIPs believe it would help improve beneficiary access to these vaccines if they were under Part B.

have proposed that the Secretary of Health and Human Services use existing authority to provide for Medicare Part B coverage for "additional preventive services" to include a broader range of adult vaccinations than those already specifically provided for in statute.[58] Under this authority, the Secretary may include certain services under Part B if, among other things, they are recommended with a grade of A or B by the U.S. Preventive Services Task Force (USPSTF). HHS has determined that because USPSTF has not made such a recommendation in relation to vaccines, this authority is inapplicable.[59]

Consolidating Medicare coverage of all vaccinations under Medicare Part B has broad support among stakeholders, but it would require legislation and would likely increase federal Medicare costs. HHS has acknowledged that consolidating vaccinations under Part B could address some administrative challenges, but has determined that the department does not have the authority to do so. In 2005, before Part D was implemented, HHS reported that because vaccinations have traditionally been provided by physicians, coverage under both Part B and Part D raised administrative complexity issues for physicians and Part D.[60] And while some stakeholders have suggested that CMS has administrative authority to cover routinely recommended vaccinations under Part B, CMS officials told us that additional legislation would be needed to do so. Further, the Congressional Budget Office (CBO) and CMS studies have reported that although consolidating vaccinations under Part B could decrease beneficiaries' cost sharing, it could also increase federal Medicare costs. In 2009, CBO estimated the federal cost of proposed legislation consolidating coverage of all vaccinations under Part B at $1.5 billion over the 10-year period 2010-2019.[61] According to CBO

[58]Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, § 101(a)(1)(B), 122 Stat. 2494, 2496 (adding a new subsection (ddd) to SSA § 1861).

[59]USPSTF typically assigns letter grades to preventive services it evaluates, recommending those services graded A or B for routine use in medical practice. However, USPSTF does not currently evaluate or make recommendations on vaccinations, instead referring to ACIP recommendations—acknowledging that ACIP's review methods may differ from its own.

[60]See HHS, *Report to Congress: Transitioning Medicare Part B Covered Drugs to Part D* (Baltimore, Md.: 2005) (required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. No. 108-173, § 101, 117 Stat. 2066, 2150 (adding SSA § 1860D-42(c) (codified at 42 U.S.C. § 1395w-101 note)).

[61]CBO, *Estimate of the Effects on the Deficit of H.R.3962, the Affordable Health Care for America Act, as Passed by the House of Representatives* (Nov. 20, 2009).

officials, this amount was due, in part, to an assumption that more Medicare beneficiaries would receive the shingles vaccine through Medicare if it were covered under Part B since more beneficiaries have Part B coverage than have Part D coverage and because it would be easier for physicians to provide and administer vaccinations under Part B. CBO's estimate also took into account the likelihood of new vaccines being developed and covered by Medicare. Earlier, in 2007, when MedPAC recommended that Part B—and not Part D—should cover routinely recommended vaccinations, CBO estimated that consolidating all vaccines under Part B would increase Medicare spending by $0 to $50 million for 1 year and by $0 to $1 billion over 5 years.[62] These findings—that the costs to Medicare could increase if all vaccines were covered under Part B—are consistent with a more recent CMS-contracted report that found that covering all vaccinations under Part B could decrease beneficiaries' cost sharing for vaccinations currently covered under Part D but would likely increase federal Medicare costs.[63]

While available estimates show increased costs to Medicare if all vaccinations were consolidated under Part B, two recent developments could affect future costs to Medicare by increasing the number of individuals obtaining some vaccinations prior to enrolling in Medicare. First, as of September 23, 2010, PPACA mandated "first-dollar coverage" for vaccinations, requiring private insurance plans to cover all ACIP-

[62]According to MedPAC staff, CBO does not provide specific estimates for the cost of the commission's recommendations; instead, CBO classifies those estimated costs within buckets of cost range estimates. The ranges of $0 to $50 million for 1 year and $0 to $1 billion for 5 years were CBO's smallest cost increase estimate buckets for 1 and 5 years, respectively.

[63]G. Marrufo et al., *Estimating the Effects of Consolidating Drugs under Part D or Part B* (Acumen, LLC, Sept. 2011). The study analyzed data for Part D beneficiaries who received vaccinations covered under Part D in 2007 and estimated the change in costs to both Part D beneficiaries and the Medicare program had the vaccinations been paid for by Part B.

recommended vaccinations with no patient cost sharing.[64] This coverage may provide an incentive for individuals to obtain the shingles vaccination between the ages of 60—when the vaccine is currently first recommended—and 64, if they have private insurance that would make the vaccine available to them at no cost, as opposed to waiting until age 65 or older when they are in Medicare and responsible for more cost sharing. Also, physicians and pharmacies may be more likely to stock the shingles vaccine if more individuals have coverage. Similarly, more beneficiaries may enter Medicare up-to-date on their Td/Tdap boosters because these boosters will also be available with first-dollar coverage under private health insurance plans. Second, in March 2011, the Food and Drug Administration approved the shingles vaccine for individuals beginning at age 50—10 years earlier than the currently recommended age of 60—potentially increasing the number of individuals entering Medicare having already received the onetime shingles vaccination. In June 2011, ACIP considered reducing its recommendation to age 50, but declined to do so, citing, among other factors, the ongoing problem with shingles vaccine supply. However, ACIP also indicated that it would reconsider its recommendation when sustained supplies of the shingles vaccine became more available.

[64]Pub. L. No. 111-148, § 1001, 124 Stat. 130 (adding § 2713 to the Public Health Service Act). Private health care plans in existence as of March 23, 2010, are considered grandfathered plans that do not have to comply with certain PPACA coverage requirements, including first-dollar coverage for vaccinations. *See* Pub. L. No. 111-148, § 1251, 124 Stat. 161. However, plans will lose their grandfathered status if they significantly cut benefits or increase beneficiary cost sharing. HHS, in conjunction with the Departments of the Treasury and Labor, estimated that a substantial fraction of plans will enact changes and relinquish their grandfathered status. For example, the departments estimated that from 39 percent to 69 percent of private employer-sponsored plans will relinquish their grandfathered status by 2013. *See,* Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 34538, 34553, 34557 (June 17, 2010) (provisions relating to maintenance of grandfather status codified at 26 C.F.R. § 54.9815—1251T(g), 29 C.F.R. § 2590.715—1251 and 45 C.F.R. § 147.140).

Increasing Pharmacists' Ability to Provide Vaccinations Could Improve Access in Several States but Would Require State Authorization

Pharmacy groups have recommended increasing the involvement of pharmacies in promoting and administering vaccinations as a way to improve access, but doing so would require authorization in some states. Pharmacy groups, such as the American Pharmacists Association and the National Association of Chain Drug Stores, as well as a CDC official and other stakeholders participating in our IOM-facilitated discussion, reported that pharmacies can be convenient locations for vaccinations given pharmacies' multiple sites in the community and the ease with which beneficiaries can access pharmacy services.[65] In addition, a pharmacy representative participating in our facilitated discussion noted that unlike most physicians, pharmacies can promote vaccinations to a large audience through posters and billboards and have an economic incentive to do so.

The American Pharmacists Association, the National Association of Chain Drug Stores, and others have advocated for allowing all pharmacists to also administer shingles and Td/Tdap vaccines in all states. However, according to the American Pharmacists Association, not all states authorize pharmacists to administer all Part D-covered vaccines. Pharmacists are allowed to administer at least some vaccinations in all 51 states, but according to the American Pharmacists Association, as of October 2011, pharmacists in 4 states did not have the authority to administer shingles vaccinations and pharmacists in 9 states did not have the authority to administer Td/Tdap vaccinations.

Conclusions

Determining the barriers affecting Medicare beneficiaries' access to recommended Part D-covered vaccines is a complex undertaking. In looking at the Part D-covered vaccines that are routinely recommended, a multitude of factors stand out, complicating any recommendation for how to improve access. Physicians and pharmacies do not always stock the vaccines, for many reasons, including cost, administrative billing challenges, and supply issues. Physicians do not always recommend the vaccinations to beneficiaries, and even when they do, beneficiaries may decline them. For the shingles vaccine, its relatively recent approval and limited supply in the years since it was approved are likely contributors to

[65]National Association of Chain Drug Stores officials and most surveyed pharmacies—69 percent—reported that another way to increase access to all vaccinations would be to cover them under Part D because pharmacies, as in-network Part D providers, can more easily check beneficiaries' coverage and submit reimbursements.

the relatively low coverage rate. Among the many contributing factors affecting beneficiary access to these Part D-covered vaccinations, no single factor can be considered to be key.

At the same time, it is well recognized that the complexity of the Medicare Part D billing processes has created administrative challenges for physicians, the traditional providers of vaccinations under Part B, and for beneficiaries, who often end up seeking reimbursement for Part D vaccines themselves. An administrative solution to physicians' challenges would be to cover vaccines under Part B, but this would increase Medicare program costs and would need to consider pharmacists' role in providing additional access to vaccinations. CMS has taken appropriate steps to provide guidance with regard to how Part D plans can facilitate physician billing, recognizing challenges. But stakeholders reported that awareness of current billing options is limited and that verifying beneficiary coverage and billing under Part D remains burdensome for physicians. As the supply of the shingles vaccine increases and as new vaccines are approved and recommended, facilitating beneficiary access by reducing physicians' barriers to billing under Part D will be more important. Fully exploring Medicare program options now to reduce these administrative burdens while minimizing costs would be appropriate.

Recommendation for Executive Action

To help improve the ability of Medicare beneficiaries to obtain routinely recommended vaccinations, we recommend that the Administrator of CMS explore options and take appropriate steps to address administrative challenges, such as physicians' difficulty in verifying beneficiaries' coverage and billing for Part D-covered vaccinations.

Agency Comments

We provided a draft of this report to HHS for its review and comment. HHS's letter and general comments are reprinted in appendix VIII. HHS concurred with our recommendation and noted that for 2012, CMS has taken steps to encourage Part D plans to offer vaccines at low or no cost and encourage beneficiaries to utilize the vaccination benefit. CMS also agreed that a multitude of factors affect beneficiaries' access to routinely recommended vaccinations covered by Part D, and indicated that the agency would continue to explore options to address the administrative challenges associated with the Part D program. HHS also provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the Secretary of Health and Human Services and other interested parties. In addition, the report is available at no charge on GAO's website at http://www.gao.gov.

If you or your staffs have any questions or need additional information, please contact me at (202) 512-7114 or iritanik@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff members who made key contributions to this report are listed in appendix IX.

Katherine Iritani
Director, Health Care

Appendix I: Scope and Methodology

To accomplish our objectives, we reviewed national survey data from the Centers for Disease Control and Prevention (CDC), analyzed Medicare data on beneficiaries and vaccinations reimbursed under Part D, and surveyed nationally representative samples of primary care physicians and pharmacies and all 51 State Health Insurance Assistance Programs (SHIP)—state agencies that provide counseling and assistance to Medicare beneficiaries. In addition, we conducted a facilitated discussion with key stakeholders.

We also obtained information on recommended vaccinations for adult Medicare beneficiaries by reviewing recommendations of and interviewing officials from the Centers for Medicare & Medicaid Services (CMS), CDC and its Advisory Committee on Immunization Practices (ACIP), and the National Vaccine Advisory Committee.[1] We also interviewed officials from (1) the Medicare Payment Advisory Commission, (2) the Department of Health and Human Services' Agency for Healthcare Research and Quality, (3) the Infectious Diseases Society of America, (4) the National Network for Immunization Information, (5) the Partnership for Prevention, (6) AARP,[2] (7) Families USA, (8) the Biotechnology Industry Organization, (9) TransactRx, (10) the National Association of Chain Drug Stores, (11) the American Pharmacists Association, (12) the National Community Pharmacists Association, (13) the American College of Physicians, (14) the American Medical Association, (15) the American Academy of Family Physicians, (16) the American Health Care Association, (17) the American Association of Homes and Services for the Aging, (18) the American Medical Directors Association, and (19) six Medicare Part D plan sponsors that cover almost 40 percent of all Part D beneficiaries. Additionally, we reviewed relevant laws, regulations, and guidance on coverage of routinely recommended adult vaccinations under Medicare and conducted a literature review.

We conducted this performance audit from September 2010 to December 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to

[1]The National Vaccine Advisory Committee makes recommendations to the Director of the Department of Health and Human Services' National Vaccine Program, which is responsible for coordinating and ensuring collaboration among federal agencies involved in vaccination and immunization activities.

[2]The organization was formerly known as the American Association of Retired Persons.

obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Analysis of CDC National Survey Data

To determine the extent to which Medicare beneficiaries age 65 and older have received the routinely recommended vaccinations that are covered under Part D, we obtained data from two national health surveys administered by CDC's National Center for Health Statistics—2007 data from the National Immunization Survey and 2008 and 2009 data from the National Health Interview Survey (NHIS).[3] We obtained data on the percentage of individuals age 65 and older who reported ever receiving a vaccination to prevent shingles or vaccinations to help prevent tetanus and diphtheria (Td vaccine) in the prior 10 years. We also obtained this information for a number of subgroups, including those with and without Part D coverage.

Analysis of Medicare Data

We analyzed Medicare enrollment and Part D prescription drug event data to determine the extent to which Part D beneficiaries—both those enrolled in stand-alone prescription drug plans and those enrolled in Medicare Advantage Part D prescription drug plans—had vaccinations reimbursed by Part D. We analyzed Medicare enrollment data to identify beneficiaries with Part D coverage. Our analyses included beneficiaries who were ever enrolled in Part D in 2007, 2008, or 2009 and excluded beneficiaries under age 65 and beneficiaries enrolled in Part D plans with restricted enrollment—employer-sponsored plans, religious fraternal benefit plans, CMS demonstrations, and programs of all-inclusive care for the elderly.

To determine the number of Part D beneficiaries who had vaccinations reimbursed by Part D, we analyzed prescription drug event data from 2007 through 2009 to identify claims with National Drug Codes (a unique product identifier for human drugs assigned by the Food and Drug Administration) associated with Part D-covered vaccinations, including shingles and Td/Tdap vaccinations. We analyzed the data for several subgroups, including by age, sex, race, Part D plan type (stand-alone and

[3]The most recent NHIS data available for our analysis were those from 2009.

Medicare Advantage Part D prescription drug plans), and low-income subsidy (LIS)/non-LIS status. We also analyzed the prescription drug event data from 2007 through 2009 to determine beneficiaries' cost sharing for Part D vaccinations and the method of reimbursement for the vaccinations.

We also estimated the percentage of Medicare beneficiaries who were immunocompromised since shingles vaccinations are contraindicated for individuals with immunocompromising conditions. ACIP identified immunocompromising conditions that would contraindicate shingles vaccinations when it made its recommendation.[4] We analyzed Medicare Hierarchical Condition Categories for 2007 and 2008 to identify beneficiaries with categorizations that indicated that they may have certain immunocompromising conditions[5] and analyzed Medicare Part B fee-for-service data and Part D prescription drug event data to identify beneficiaries whose drug regimens indicated that they may have immunocompromising conditions.[6]

Survey of Physicians

To identify factors that affect Medicare beneficiaries' access to routinely recommended vaccinations covered under Part D, we surveyed a nationally representative sample of 6,500 primary care physicians—family and internal medicine physicians. We obtained information on common physician practices for the shingles and Td/Tdap vaccinations covered under Part D and, for comparison, the pneumococcal vaccination covered under Part B.

We developed a mostly closed-ended questionnaire in which physicians selected from a list of possible responses, or selected responses on a three-point scale (i.e., classifying a factor as a major barrier, a minor barrier, or not a barrier). We pretested the questionnaire with three

[4]CDC, "Prevention of Herpes Zoster: Recommendations of the Advisory Committee on Immunization Practices (ACIP)," *Morbidity and Mortality Weekly Report*, vol. 57, no. 05 (2008): 1-30.

[5]The most recent Hierarchical Condition Categories (a classification system used by CMS to group certain medical conditions) data available for our analysis were those from 2008.

[6]We used data from the Healthcare Common Procedure Coding System to identify fee-for-service claims in which beneficiaries utilized a drug associated with an immunocompromising condition.

primary care physicians and obtained comments on the survey from four physician professional organizations. We revised the questionnaire on the basis of the pretests and comments.

Physicians employed by a federal agency and physicians who had not provided primary care to Medicare beneficiaries age 65 and older since January 1, 2008, were not eligible to participate. We used Medicare national provider identifier data to select a random sample of physicians according to three stratifications: states, urban/rural geography, and physician vaccination rates.

- **States**: We selected 20 states, including the District of Columbia, to oversample based upon state Medicare populations, regional diversity, and beneficiary vaccination rates for both Part B-covered and Part D-covered vaccinations.[7]

- **Urban/rural geography**: We stratified the sample by the area in which the physician practiced.

- **Physician high/medium/low vaccination rate**: We stratified the sample by physician-level vaccination rates to ensure that the survey captured the experiences of physicians involved in providing vaccinations and those less involved in providing vaccinations. We classified physicians as having a high, medium, or low vaccination rate based upon the proportion of Medicare beneficiaries served by the physician who had received a Part B-covered or Part D-covered vaccination or a vaccination prescription from the physician.[8]

We fielded the questionnaire from December 2010 through March 2011 and received complete responses from 1,798 eligible physicians, for an overall response rate of 30 percent (we determined that 560 physicians in our original sample were not eligible, for example, because they were no longer in practice or were federal employees). We analyzed physician responses using standard descriptive statistics. Results were weighted to project to the national level. All estimates were based on self-reported information provided by the survey respondents and have a margin of

[7]State-level vaccination rates were calculated using 2009 Medicare Part B and Part D data.

[8]Physician vaccination rates were calculated using 2009 Medicare Part B and Part D data.

error of plus or minus 8 percentage points or less at the 95 percent confidence level, unless otherwise noted.

We performed checks on survey responses to identify inconsistent answers and conducted a nonresponse bias analysis to determine whether any bias was introduced in the results by the absence of responses from some members of the sample. Based on the results of our nonresponse bias analysis, we adjusted our survey analysis weights to ensure that physicians were appropriately represented in our study. We additionally performed statistical testing to determine whether physician practice characteristics (such as practice size or the percentage of Medicare beneficiaries that physicians reported serving) influenced physicians' responses to key survey questions.

Based on our systematic survey processes and nonresponse bias analysis, we determined that the questionnaire results were representative of primary care physicians nationally and determined that the data were sufficiently reliable for our purposes.

Survey of Pharmacies

To identify factors that affect Medicare beneficiaries' access to routinely recommended vaccinations covered under Part D, we also surveyed a nationally representative sample of 1,500 pharmacies. As with our physician survey, we obtained information on common practices for the shingles and Td/Tdap vaccinations covered under Part D and, for comparison, the pneumococcal vaccination covered under Part B.

We developed a mostly closed-ended questionnaire in which pharmacies selected from a list of possible responses, or selected responses on a three-point scale (i.e., classifying a factor as a major barrier, a minor barrier, or not a barrier). We pretested the questionnaire with five pharmacies and obtained comments on the survey from two pharmacy professional organizations. We revised the questionnaire on the basis of the pretests and comments.

Pharmacies operated by a federal agency and pharmacies that had not served Medicare beneficiaries age 65 and older since January 1, 2008, were not eligible to participate. We used Medicare national provider identifier data to select a random sample of pharmacies according to four stratifications: states, urban/rural geography, pharmacy vaccination rate, and pharmacy type.

- **States**: We selected 20 states, including the District of Columbia, to oversample based upon state Medicare populations, regional diversity, and beneficiary vaccination rates for both Part B-covered and Part D-covered vaccinations.[9]

- **Urban/rural geography**: We stratified the sample by the area in which the pharmacy was located.

- **Pharmacy high/low vaccination rate**: We stratified the sample by pharmacy-level vaccination rates to ensure that the survey captured the experiences of pharmacies involved in providing vaccinations and those less involved in providing vaccinations. We classified each pharmacy within the sampling frame as having either a high or low vaccination rate based upon the proportion of Medicare beneficiaries served by the pharmacy who obtained a Part D-covered vaccine or received a vaccination from the pharmacy.[10]

- **Pharmacy type**: We stratified the sample by three categories of pharmacies—chain, franchise, and independent pharmacies.

We fielded the questionnaire from December 2010 through March 2011 and received complete responses from 694 eligible pharmacies, for an overall response rate of 48 percent (we determined that 48 pharmacies in our original sample were not eligible, for example, because they were no longer in business). We analyzed pharmacy responses using standard descriptive statistics. Results were weighted to project to the national level. All estimates were based on self-reported information provided by the survey respondents and have a margin of error of plus or minus 8 percentage points or less at the 95 percent confidence level, unless otherwise noted.

We performed checks on survey responses to identify inconsistent answers and conducted a nonresponse bias analysis to determine whether any bias was introduced in the results by the absence of responses from some members of the sample. Based on the results of our nonresponse bias analysis, we adjusted our survey analysis weights

[9]State-level vaccination rates were calculated using 2009 Medicare Part B and Part D data.

[10]Pharmacy vaccination rates were calculated using 2009 Medicare Part D data.

to ensure that pharmacies were appropriately represented in our study. We additionally performed statistical testing to determine whether pharmacy characteristics and practices (such as pharmacy type and practices for offering and recommending vaccinations) influenced responses to key survey questions.

Based on our systematic survey processes and nonresponse bias analysis, we determined that the questionnaire results were representative of pharmacies nationally and determined that the data were sufficiently reliable for our purposes.

Survey of SHIPs

We also conducted a web-based survey of SHIPs in all 51 states—we refer to the District of Columbia as a state throughout this report—to obtain information on beneficiary questions and concerns related to the shingles and Td/Tdap vaccinations covered under Part D and, for comparison, the pneumococcal vaccination covered under Part B. We developed a mostly closed-ended questionnaire in which SHIP officials selected from a list of possible responses. We pretested the questionnaire with SHIP officials from three states—California, Louisiana, and Utah. We additionally obtained comments on the survey from Families USA, a beneficiary advocacy group that contracts with CMS to manage the SHIPs and serves as a liaison between CMS and the SHIPs. We revised the questionnaire on the basis of the pretests and comments.

We fielded the questionnaire from November 2010 through March 2011 and received a 100 percent response rate. We analyzed SHIP responses using standard descriptive statistics. We relied on the data as reported by the SHIPs and performed checks on survey responses to identify inconsistent answers. We determined that these data were sufficiently reliable for the purposes of our report.

Facilitated Discussion with Stakeholders

To examine the recommendations of government agencies, advisory bodies, professional organizations, and other stakeholders to improve beneficiaries' access to the routinely recommended vaccinations covered under Medicare Part D, we contracted with the National Academy of Sciences to have the Institute of Medicine (IOM) facilitate a discussion with stakeholders on vaccinations covered under Part D. We told institute officials the type of participants we preferred, and they obtained input from us, IOM members, advocacy groups, and individual experts in the field to select stakeholders for the discussion. Invitations to participate were issued by IOM. In total, 20 experts—representing government

agencies; health advisory bodies with involvement in vaccines; physician, pharmacy, or insurance professional organizations; and health care researchers—participated (see table 11 for a list of participants and their affiliations).[11] The meeting was moderated by one of the participants, a physician/researcher with expertise in preventive services. The group was not asked to reach consensus on any issues, and the institute was not asked to produce or publish a report of the meeting. We observed the meeting and subsequently reviewed its transcript and documents provided by meeting participants. Participant comments from the meeting represent individual or organizational statements, not a consensus of the group as a whole, and should not be interpreted to represent the views of IOM or all experts in the field of preventive services or vaccinations.

[11]Several members represented both professional organizations and advisory bodies.

Table 11: IOM-Facilitated Discussion Participants

Name	Title	Organization
Phyllis A. Arthur	Senior Director, Vaccines, Immunotherapeutics and Diagnostics Policy	Biotechnology Industry Organization
Guthrie S. Birkhead, MD, MPH	Chair	National Vaccine Advisory Committee
	Deputy Commissioner	Office of Public Health, New York State Department of Health
Doug Campos-Outcalt, MD, MPA	Liaison to the Advisory Committee on Immunization Practices	American Academy of Family Physicians
	Associate Head, Family and Community Medicine	University of Arizona College of Medicine, Phoenix
Margaret S. Coleman, Ph.D.	Economist/Health Scientist	Centers for Disease Control and Prevention
Elisabeth Daniel	Senior Associate	Avalere Health
Claire Hannan, MPH	Executive Director	Association of Immunization Managers
Rafael Harpaz, MD, MPH	Captain, U.S. Public Health Service	Centers for Disease Control and Prevention
Laura Hurley, MD, MPH	General Internist and Researcher	Private practice
Scott Jauch	Senior Manager	Avalere Health
Robert S. Lawrence, MD (Moderator)	Professor of Environmental Health Sciences, Health Policy, and International Health	Center for a Livable Future Professor Johns Hopkins Bloomberg School of Public Health
Martin G. Myers, MD	Executive Director	National Network for Immunization Information
Margaret Nowak	Director	Avalere Health
Edmund J. Pezalla, MD, MPH	National Medical Director for Pharmacy Policy and Strategy	Aetna Pharmacy Management
	Member	Pharmaceutical Care Management Association
Leigh Purvis	Senior Strategic Policy Advisor	AARP
Mitchel C. Rothholz, RPh, MBA	Chief of Staff	American Pharmacists Association
William Schaffner, MD	Professor and Chair	Department of Preventive Medicine Vanderbilt University School of Medicine
	President	National Foundation for Infectious Diseases
	Member	Advisory Committee on Immunization Practices
	Member	American College of Physicians
Elise Smith	Vice President, Finance Policy	American Health Care Association
Alexandra Stewart, J.D.	Assistant Professor	Department of Health Policy, George Washington University School of Public Health and Health Services
L.J. Tan, M.S., Ph.D.	Liaison to the Advisory Committee on Immunization Practices and Director, Medicine and Public Health	American Medical Association
Cynthia G. Tudor, Ph.D.	Director, Medicare Drug Benefit and Medicare Parts C & D Data Group	Centers for Medicare & Medicaid Services

Source: GAO.

Literature Review

We also conducted a literature review of articles from peer-reviewed journals, as well as letters and reports, including those provided by advisory bodies and professional organizations, to identify stakeholder findings and recommendations. This review resulted in 65 items that we determined to be relevant to our objectives. To conduct this review, we searched 16 reference databases for articles published from January 1, 2005, through August 10, 2010, using a combination of search terms, such as “Medicare” and “vaccination.” In addition to searching the databases, we identified other potentially relevant research through our background research, interviews, and other audit work.

Appendix II: Shingles Risk, Prevalence, and Vaccine Supply

Shingles Risk and Prevalence

Shingles, also called herpes zoster, is a viral infection that produces a painful, blistering rash with few treatment options. The rash results from a reactivation of the virus that causes chicken pox (varicella). In more than 1 in 10 cases, shingles may also cause persistent, debilitating pain at the site of the rash that can last for months or years after the blisters have healed, a condition known as postherpetic neuralgia. In addition, at least 1 in 10 individuals who get shingles have a rash that involves an eye, which can result in facial scarring and loss of vision. Finally, by one estimate, about 3 percent of those with shingles will be hospitalized, though deaths are uncommon. Few treatment options exist for shingles. Prompt treatment—within 72 hours—with oral antiviral drugs can decrease the severity and duration of shingles with varying degrees of success, though not all patients recognize the symptoms in time to start prompt treatment.

Since almost all Americans have had chicken pox, almost all—over 98 percent—are at risk for shingles, with older adults being more at risk for both shingles and postherpetic neuralgia. Based on available data, CDC estimates that 1 in 3 Americans—and half of those who live to 85—will develop shingles in their lifetime, with about 1 million episodes of shingles in the United States each year.[1] The most important risk factor for the development of both shingles and postherpetic neuralgia is age, with much of the increased risk beginning at age 50. According to CDC, effectively evaluating the risks for recurrent shingles (a second or subsequent episode) in immunocompetent persons requires large populations, long-term follow-up, adequate duration, and laboratory confirmation. Although data are limited, certain studies suggest a recurrence rate that is comparable to the rate of initial episodes.

Shingles Vaccine (Zostavax)

A vaccine for shingles—called Zostavax—was licensed by the Food and Drug Administration in 2006.[2] In clinical trials, the vaccine reduced the risk of shingles in adults age 60 and older by about half and reduced the

[1]Shingles is not a notifiable condition in the United States, meaning that health care providers are not required to notify authorities of cases of shingles. Shingles incidence has been inferred from a variety of studies, including national health surveys, patient records, and health plan data. See CDC, "Prevention of Herpes Zoster: Recommendations of the Advisory Committee on Immunization Practices (ACIP)," *Morbidity and Mortality Weekly Report*, vol. 57, no. 05 (2008): 1-30.

[2]Merck & Co., Inc. is the sole manufacturer of Zostavax.

incidence of postherpetic neuralgia by about two-thirds. The vaccine has not been determined effective to treat shingles or postherpetic neuralgia.

A single dose of shingles vaccine is recommended for most adults age 60 and older. A person with certain immunocompromising conditions (such as the human immunodeficiency virus) or a person with severe immune deficiencies caused by medical conditions or medications (such as chemotherapy in cancer patients) should not get the shingles vaccine. Using Medicare data, we estimated that from 2 to 6 percent of Medicare beneficiaries had at least one immunocompromising condition that could contraindicate the shingles vaccine.

The shingles vaccine is the only adult vaccine that must be stored frozen. To maintain a frozen supply of the vaccine, physicians and pharmacies that dispense the vaccine must have a freezer that has a separate sealed freezer door and reliably maintains an average temperature of -15 degrees Celsius (+5 degrees Fahrenheit) or colder. The vaccine must be administered within 30 minutes of removal from the freezer. The shingles vaccine manufacturer also has a refrigerated version that is not currently marketed in the United States. According to company officials, the refrigerated formulation is not currently marketed because it requires significantly more bulk varicella zoster virus than the frozen one.

Limited Supply of Shingles Vaccine Reported by Physicians and Pharmacies

Since entering the U.S. market in 2006, the shingles vaccine has been subject to supply limitations necessitating back orders. According to the sole manufacturer, the company has periodically experienced difficulty meeting demand for the relatively new product. The company produced 6 million doses of the vaccine as of 2009. (See table 12.) A representative from the manufacturer reported that while the company has typically produced about 2 million doses each year, the company anticipates producing 3.2 million doses in 2011.

Table 12: Doses of Shingles Vaccine Produced, 2006 through 2011

	2006	2007	2008	2009	2010	2011[a]
Doses (in millions)	0.3	1.7	2.1	1.9	1.7	3.2

Source: Merck & Co., Inc. data and statements.

[a]Merck projection.

In our national surveys of physicians and pharmacies, those that stock the shingles vaccine frequently cited troubles stocking the vaccine due to shortages or order backlogs, suggesting that providers are experiencing difficulty maintaining a supply of the vaccine. We estimate that nearly 8 in 10 physicians who stock the vaccine cited the shortage as a barrier—47 percent cited it as a major barrier and 29 percent as a minor barrier. More than 8 in 10 pharmacies that stock the vaccine cited the shortage as a barrier—56 percent cited it as a major barrier and 28 percent as a minor barrier.

Representatives from the manufacturer have cited two main reasons for the limited supply of the shingles vaccine. The first reason is that a key shingles vaccine ingredient was diverted to produce a different vaccine. The shingles vaccine shares a key ingredient (bulk varicella zoster virus) with the vaccine that protects against chicken pox, and in 2006 CDC's ACIP revised its recommendation for the chicken pox vaccine, increasing the recommendation from one dose to two. Company officials report that in response they assigned a higher priority to the production of chicken pox vaccine, which limited production of the shingles vaccine. The second reason cited by company officials was delays in manufacturing the vaccine caused by complexities and difficulties producing the vaccine. However, in June 2011 company officials stated that production of the vaccine would increase.

Appendix III: Centers for Disease Control and Prevention National Survey and Medicare Part D Data for Selected Demographics

This appendix includes information from CDC on the percentage of adults age 65 and older reporting ever receiving a shingles vaccination or receiving a Td vaccination in the previous 10 years by selected demographic groups as of 2009 (see table 13); for 2007 through 2009 (see table 14); and by insurance coverage (see table 15). This appendix also includes additional Part D data on vaccinations reimbursed by Part D for selected demographic groups from 2007 through 2009 (see table 16).

Table 13: Percentage of Adults Age 65 and Older Reporting Ever Receiving a Shingles Vaccination or Receiving a Td Vaccination in Previous 10 Years, 2009

Demographic		Percentage receiving a shingles vaccination (lower bound, upper bound)	Percentage receiving a Td vaccination[a] (lower bound, upper bound)
Total		11.0 (10.0, 12.0)	52.8 (51.0, 54.5)
Age	65-74	11.6 (10.1, 13.3)	58.3 (56.0, 60.6)
	75-84	10.8 (9.2, 12.7)	46.7 (43.8, 49.5)
	85+	8.8 (6.7, 11.4)	44.1 (39.1, 49.2)
Sex	Female	11.7 (10.4, 13.1)	47.8 (45.5, 50.1)
	Male	10.1 (8.6, 11.9)	59.2 (56.6, 61.8)
Race	Non-Hispanic White only	12.4 (11.1, 13.7)	54.9 (52.9, 56.9)
	Non-Hispanic Black only	4.7 (2.7, 7.9)	41.6 (36.1, 47.2)
	Hispanic	3.8 (2.4, 6.1)	46.5 (41.6, 51.5)
	Non-Hispanic Asian only	10.4 (7.2, 14.9)	38.2 (31.2, 45.7)
	Non-Hispanic Other	7.3 (3.0, 17.0)	71.0 (54.0, 83.6)

Source: CDC National Health Interview Survey.

Notes: The 65 and older population surveyed closely corresponds to the Medicare population. Lower and upper bounds display 95 percent confidence levels for estimates.

[a]Data include Td vaccinations administered as a treatment or as a preventive measure.

Table 14: Percentage of Adults Age 65 and Older Reporting Ever Receiving Shingles Vaccination or Receiving Td Vaccination in the Previous 10 Years, 2007 through 2009

Vaccination	2007 (lower bound, upper bound)	2008 (lower bound, upper bound)	2009 (lower bound, upper bound)
Shingles[a]	2.3 (1.5, 3.5)	7.6 (6.6, 8.6)	11.0 (10.0, 12.0)
Td[b]	44.1 (40.7, 47.6)	51.9 (50.0, 53.8)	52.8 (51.0, 54.6)

Source: CDC National Health Interview Survey (2008 and 2009) and National Immunization Survey (2007).

Notes: The age 65 and older population surveyed closely corresponds to the Medicare population. Lower and upper bounds display 95 percent confidence levels for estimates.

[a]National estimates of the percentage of adults age 65 and older who reported ever receiving a shingles vaccination.

[b]National estimates of the percentage of adults age 65 and older who reported receiving a Td vaccination in the previous 10 years. Data include Td vaccinations administered as a treatment or as a preventive measure.

Table 15: Percentage of Adults Age 65 and Older Reporting Ever Receiving Shingles Vaccination or Receiving Td Vaccination in the Previous 10 Years, by Insurance Coverage, 2009

		Without Part D coverage		With Part D coverage	
Vaccination	All respondents (lower bound, upper bound)	No other coverage[a] (lower bound, upper bound)	With private or other coverage[a] (lower bound, upper bound)	No other coverage (lower bound, upper bound)	With private or other coverage[a] (lower bound, upper bound)
Shingles[b]	11.0 (10.0, 12.0)	10.7 (9.5, 12.1)	13.4 (11.4, 15.8)	11.5 (10.0, 13.2)	14.6 (12.0, 17.7)
Td[c]	52.8 (51.0, 54.5)	52.8 (50.6, 55.0)	54.8 (51.8, 57.8)	52.6 (49.6, 55.5)	56.0 (51.5, 60.3)

Source: CDC National Health Interview Survey.

Notes: The age 65 and older population surveyed closely corresponds to the Medicare population. Lower and upper bounds display 95 percent confidence levels for estimates.

[a]Other coverage includes Medicaid, a state-sponsored or other government-sponsored health plan, or a military plan.

[b]National estimates of the percentage of adults age 65 and older who reported ever receiving a shingles vaccination.

[c]National estimates of the percentage of adults age 65 and older who reported receiving a Td vaccination in the previous 10 years. Data include Td vaccinations administered as a treatment or as a preventive measure.

Table 16: Vaccinations Reimbursed by Part D for Individuals Age 65 and Older by Demographic Group, 2007 through 2009

Demographic		Percentage of Part D beneficiaries reimbursed for shingles vaccinations	Percentage of Part D beneficiaries reimbursed for Td/Tdap vaccinations
Total		4.59	0.49
Plan type	Medicare Advantage prescription drug plans	5.33	1.44
	Other Part D prescription drug plans	4.27	0.09
LIS status	Non-LIS	5.93	0.63
	LIS	1.87	0.21
Age	65-74	5.46	0.57
	75-84	4.36	0.46
	85+	1.85	0.29
Sex	Female	4.83	0.46
	Male	4.19	0.54
Race	White	5.06	0.51
	Black	0.74	0.18
	Hispanic	1.26	0.43
	Asian	7.42	0.71
	Other[a]	4.32	1.08

Source: GAO analysis of 2007 through 2009 Medicare Part D data.

Note: This table shows Part D data for beneficiaries age 65 and older ever enrolled in a Part D plan from 2007 through 2009, excluding those enrolled in employer plans, religious fraternal benefit plans, CMS demonstrations, and programs of all-inclusive care for the elderly.

[a]Includes American Indians.

Appendix IV: Selected Results of the GAO 2010 Physician Survey

This appendix summarizes the results from questions we asked primary care physicians on common practices for the Part D-covered shingles and Td/Tdap vaccines and, for comparison, the Part B-covered pneumococcal vaccine. We conducted a national mail and telephone survey of 6,500 primary care—family and internal medicine—physicians and weighted the responses to provide nationally representative estimates.

The following tables show selected survey information on the frequency of physician vaccination recommendations (table 17); frequency of beneficiary declinations (table 18); reasons for beneficiary declinations (table 19); stocking practices (table 20); barriers to stocking, administering, or recommending the shingles, Td/Tdap, and pneumococcal vaccines (tables 21 through 29); awareness and use of web-assisted billing systems (table 30); and recommendations to make it easier for physicians to stock and administer all routinely recommended vaccines (table 31).

Table 17: Frequency of Physician Vaccination Recommendations

	Shingles percentage (lower bound, upper bound)	Td/Tdap percentage (lower bound, upper bound)	Pneumococcal percentage (lower bound, upper bound)
Always recommend the vaccination	33 (29, 37)	46 (40, 52)	78 (74, 81)
Usually recommend the vaccination	35 (29, 40)	28 (24, 33)	19 (16, 22)
Recommend the vaccination about half the time	12 (9, 14)	9 (5, 12)	2 (1, 4)
Occasionally recommend the vaccination	19 (15, 22)	16 (13, 19)	1 (0, 2)
Never recommend the vaccination	2 (1, 3)	1 (1,2)	0 (0, 0)

Source: GAO 2010 Physician Survey.

Notes: The sampling frame for our survey included practicing family and internal medicine physicians in the United States who were not federal employees and who provided primary care to Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

Percentages may not total to 100 percent due to rounding.

Table 18: Frequency of Beneficiary Declinations after Physicians Have Recommended the Vaccinations

	Shingles percentage (lower bound, upper bound)	Td/Tdap percentage (lower bound, upper bound)	Pneumococcal percentage (lower bound, upper bound)
Never decline the vaccination	1 (0, 2)	9 (6, 12)	11 (8, 14)
Occasionally decline the vaccination	31 (28, 34)	55 (49, 60)	78 (74, 82)
Decline the vaccination about half the time	35 (31, 38)	17 (13, 20)	9 (5, 12)
Usually decline the vaccination	25 (21, 29)	14 (11, 18)	1 (1, 2)
Always decline the vaccination	2 (0, 4)	2 (0, 3)	0 (0, 0)
Do not know	6 (4, 8)	4 (2, 6)	1 (0, 1)

Source: GAO 2010 Physician Survey.

Notes: The sampling frame for our survey included practicing family and internal medicine physicians in the United States who were not federal employees and who provided primary care to Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

Percentages may not total to 100 percent due to rounding.

Excludes physicians who never recommend shingles, Td/Tdap, or pneumococcal vaccinations.

Table 19: Reasons for Beneficiary Declinations

	Shingles percentage (lower bound, upper bound)	Td/Tdap percentage (lower bound, upper bound)	Pneumococcal percentage (lower bound, upper bound)
Lack of Part D or other insurance coverage	50 (45, 54)	28 (24, 31)	N/A[a]
Difficulty affording cost sharing	48 (44, 53)	23 (20, 27)	N/A[a]
Concerns about safety	26 (23, 29)	29 (24, 33)	37 (34, 40)
Concerns about efficacy	15 (12, 18)	7 (5, 9)	11 (8, 14)
Need to obtain vaccination outside of physician's office	24 (20, 27)	8 (5,12)	4 (2, 6)

Source: GAO 2010 Physician Survey.

Notes: The sampling frame for our survey included practicing family and internal medicine physicians in the United States who were not federal employees and who provided primary care to Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

Excludes physicians who never recommend shingles, Td/Tdap, or pneumococcal vaccinations.

[a]Nearly all Medicare beneficiaries have Part B coverage for pneumococcal vaccinations, which covers the vaccination with no beneficiary cost sharing.

Table 20: Physician Stocking Practices

	Shingles percentage (lower bound, upper bound)	Td/Tdap percentage (lower bound, upper bound)	Pneumococcal percentage (lower bound, upper bound)
Stock the vaccine and it is administered in my office	31 (26, 36)	83 (79, 87)	91 (89, 94)
Refer beneficiaries to a pharmacy to purchase the vaccine, and it is administered in my office	26 (22, 31)	4 (1, 7)	1 (0, 1)
Refer beneficiaries to a pharmacy to purchase the vaccine, and it is administered at the pharmacy	28 (22, 34)	3 (1, 6)	3 (1, 5)
Refer beneficiaries to the Public Health Department, and the vaccine is obtained and administered at the Public Health Department	7 (4, 10)	7 (4, 9)	3 (2, 5)
Refer beneficiaries to another clinic or practice, and the vaccine is obtained and administered there	5 (3, 7)	2 (0, 4)	2 (0, 3)
Other	3 (1, 5)	1 (1, 1)	0 (0, 0)

Source: GAO 2010 Physician Survey.

Notes: The sampling frame for our survey included practicing family and internal medicine physicians in the United States who were not federal employees and who provided primary care to Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

Table 21: Barriers to Stocking, Administering, or Recommending the Shingles Vaccine, Reported by All Physicians

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Cost of purchasing vaccine stock	86 (82, 90)	66 (62, 71)	19 (14, 24)
Low Medicare reimbursement for the cost and/or administration of the vaccine	87 (84, 90)	66 (62, 69)	21 (18, 25)
Inconsistent Part D plans' coverage and reimbursement rates	93 (90, 95)	76 (72, 80)	17 (13, 20)
The time and effort required to assess beneficiary Medicare coverage for the vaccine and pursue Medicare reimbursement for providing and/or administering the vaccine	84 (80, 88)	62 (57, 67)	22 (18, 25)
Trouble stocking the vaccine due to shortage/order backlog	62 (58, 66)	35 (31, 39)	27 (24, 30)
Storage difficulties (the need to store the vaccine in a refrigerator/freezer)	35 (31, 39)	17 (15, 20)	18 (14, 21)
Physician's concern about vaccine's safety	15 (11, 19)	2 (1, 3)	13 (9, 16)
Physician's concern about vaccine's efficacy	29 (24, 35)	8 (5, 11)	21 (17, 25)
Lack of, or uncertain, beneficiary demand for the vaccine	53 (48, 58)	17 (13, 20)	36 (32, 40)
Beneficiaries' lack of insurance coverage	83 (79, 87)	61 (57, 65)	22 (19, 25)
Beneficiaries' difficulty affording the cost sharing for the vaccine	85 (80, 89)	65 (60, 70)	20 (16, 24)
Beneficiaries' concern about vaccine's safety	49 (44, 54)	8 (5, 11)	41 (36, 45)
Beneficiaries' concern about vaccine's efficacy	46 (41, 52)	9 (5, 13)	37 (33, 42)
The need for beneficiaries to transport the vaccine from a pharmacy to a physician to be administered	47 (41, 52)	22 (18, 25)	25 (21, 29)

Source: GAO 2010 Physician Survey.

Notes: The sampling frame for our survey included practicing family and internal medicine physicians in the United States who were not federal employees and who provided primary care to Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

The sum of the percentages of major/minor barriers may not equal the total percentage due to rounding.

Table 22: Barriers to Stocking, Administering, or Recommending the Shingles Vaccine, Reported by Physicians Who Stock the Vaccine

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Cost of purchasing vaccine stock	75 (65, 84)	37 (28, 46)	38 (28, 47)
Low Medicare reimbursement for the cost and/or administration of the vaccine	80 (72, 88)	55 (48, 61)	26 (17, 34)
Inconsistent Part D plans' coverage and reimbursement rates	90 (82, 97)	75 (69, 82)	14 (9, 19)
The time and effort required to assess beneficiary Medicare coverage for the vaccine and pursue Medicare reimbursement for providing and/or administering the vaccine	77 (67, 88)	56 (46, 65)	22 (14, 30)
Trouble stocking the vaccine due to shortage/order backlog	76 (70, 82)	47 (39, 55)	29 (22, 36)
Storage difficulties (the need to store the vaccine in a refrigerator/freezer)	21 (15, 28)	4 (0, 8)	17 (11, 23)
Physician's concern about vaccine's safety	8 (5, 10)	1 (0, 1)	7 (4, 9)
Physician's concern about vaccine's efficacy	27 (16, 37)	8 (1, 15)	19 (12, 25)
Lack of, or uncertain, beneficiary demand for the vaccine	41 (31, 51)	8 (3, 12)	33 (25, 41)
Beneficiaries' lack of insurance coverage	84 (78, 89)	65 (59, 72)	18 (12, 25)
Beneficiaries' difficulty affording the cost sharing for the vaccine	85 (79, 91)	64 (56, 71)	21 (14, 29)
Beneficiaries' concern about vaccine's safety	51 (43, 59)	3 (1, 6)	48 (39, 57)
Beneficiaries' concern about vaccine's efficacy	46 (34, 59)	7 (1, 13)	40 (30, 49)
The need for beneficiaries to transport the vaccine from a pharmacy to a physician to be administered	21 (15, 28)	9 (4, 15)	12 (8, 16)

Source: GAO 2010 Physician Survey.

Notes: The sampling frame for our survey included practicing family and internal medicine physicians in the United States who were not federal employees and who provided primary care to Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

The sum of the percentages of major/minor barriers may not equal the total percentage due to rounding.

Table 23: Barriers to Stocking, Administering, or Recommending the Shingles Vaccine, Reported by Physicians Who Do Not Stock the Vaccine

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Cost of purchasing vaccine stock	90 (88, 93)	79 (75, 83)	11 (7, 16)
Low Medicare reimbursement for the cost and/or administration of the vaccine	90 (86, 94)	70 (66, 74)	20 (15, 24)
Inconsistent Part D plans' coverage and reimbursement rates	94 (92, 96)	76 (71, 82)	18 (13, 22)
The time and effort required to assess beneficiary Medicare coverage for the vaccine and pursue Medicare reimbursement for providing and/or administering the vaccine	86 (84, 88)	65 (59, 70)	22 (17, 26)
Trouble stocking the vaccine due to shortage/order backlog	56 (50, 62)	30 (26, 34)	26 (21, 31)
Storage difficulties (the need to store the vaccine in a refrigerator/freezer)	42 (37, 46)	23 (20, 26)	18 (13, 23)
Physician's concern about vaccine's safety	18 (13, 24)	3 (2, 4)	15 (10, 20)
Physician's concern about vaccine's efficacy	30 (25, 35)	8 (5, 12)	22 (17, 26)
Lack of, or uncertain, beneficiary demand for the vaccine	58 (53, 63)	21 (16, 26)	37 (32, 42)
Beneficiaries' lack of insurance coverage	83 (78, 88)	59 (53, 64)	24 (20, 28)
Beneficiaries' difficulty affording the cost sharing for the vaccine	85 (80, 90)	66 (59, 72)	19 (15, 24)
Beneficiaries' concern about vaccine's safety	47 (41, 54)	10 (6, 14)	37 (31, 43)
Beneficiaries' concern about vaccine's efficacy	46 (40, 52)	10 (5, 15)	36 (31, 42)
The need for beneficiaries to transport the vaccine from a pharmacy to a physician to be administered	58 (52, 64)	27 (23, 31)	31 (26, 35)

Source: GAO 2010 Physician Survey.

Notes: The sampling frame for our survey included practicing family and internal medicine physicians in the United States who were not federal employees and who provided primary care to Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

The sum of the percentages of major/minor barriers may not equal the total percentage due to rounding.

Table 24: Barriers to Stocking, Administering, or Recommending Td/Tdap Vaccines, Reported by All Physicians

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Cost of purchasing vaccine stock	41 (35, 46)	16 (13, 20)	24 (19, 30)
Low Medicare reimbursement for the cost and/or administration of the vaccine	66 (61, 71)	39 (35, 44)	27 (22, 32)
Inconsistent Part D plans' coverage and reimbursement rates	69 (65, 74)	42 (38, 46)	27 (23, 32)
The time and effort required to assess beneficiary Medicare coverage for the vaccine and pursue Medicare reimbursement for providing and/or administering the vaccine	60 (54, 65)	32 (27, 37)	28 (23, 32)
Trouble stocking the vaccine due to shortage/order backlog	24 (19, 28)	2 (1, 3)	22 (17, 26)
Storage difficulties (the need to store the vaccine in a refrigerator/freezer)	10 (7, 13)	0 (0, 1)	9 (7, 12)
Physician's concern about vaccine's safety	5 (3, 8)	0 (0, 0)	5 (2, 8)
Physician's concern about vaccine's efficacy	5 (3, 7)	0 (0, 0)	5 (3, 6)
Lack of, or uncertain, beneficiary demand for the vaccine	30 (25, 35)	5 (3, 8)	24 (20, 29)
Beneficiaries' lack of insurance coverage	54 (49, 59)	27 (23, 31)	27 (22, 32)
Beneficiaries' difficulty affording the cost sharing for the vaccine	55 (49, 60)	23 (19, 27)	32 (28, 36)
Beneficiaries' concern about vaccine's safety	30 (25, 35)	2 (1, 3)	28 (23, 33)
Beneficiaries' concern about vaccine's efficacy	21 (17, 25)	1 (0, 1)	21 (17, 25)
The need for beneficiaries to transport the vaccine from a pharmacy to a physician to be administered	14 (9, 19)	3 (1, 6)	11 (6, 16)

Source: GAO 2010 Physician Survey.

Notes: The sampling frame for our survey included practicing family and internal medicine physicians in the United States who were not federal employees and who provided primary care to Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

The sum of the percentages of major/minor barriers may not equal the total percentage due to rounding.

Table 25: Barriers to Stocking, Administering, or Recommending Td/Tdap Vaccines, Reported by Physicians Who Stock the Vaccines

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Cost of purchasing vaccine stock	35 (29, 40)	10 (8, 13)	25 (19, 31)
Low Medicare reimbursement for the cost and/or administration of the vaccine	61 (56, 66)	33 (29, 37)	28 (22, 33)
Inconsistent Part D plans' coverage and reimbursement rates	65 (60, 70)	37 (33, 40)	28 (24, 33)
The time and effort required to assess beneficiary Medicare coverage for the vaccine and pursue Medicare reimbursement for providing and/or administering the vaccine	55 (50, 59)	25 (21, 30)	29 (25, 34)
Trouble stocking the vaccine due to shortage/order backlog	22 (17, 26)	1 (0, 1)	21 (17, 25)
Storage difficulties (the need to store the vaccine in a refrigerator/freezer)	8 (7, 10)	0 (0, 1)	8 (6, 10)
Physician's concern about vaccine's safety	4 (2, 5)	0 (0, 0)	4 (2, 5)
Physician's concern about vaccine's efficacy	4 (3, 6)	0 (0, 0)	4 (3, 6)
Lack of, or uncertain, beneficiary demand for the vaccine	25 (22, 28)	4 (2, 5)	21 (19, 24)
Beneficiaries' lack of insurance coverage	49 (44, 53)	23 (20, 25)	26 (22, 31)
Beneficiaries' difficulty affording the cost sharing for the vaccine	52 (47, 57)	21 (18, 24)	31 (27, 35)
Beneficiaries' concern about vaccine's safety	28 (24, 32)	2 (1, 3)	26 (23, 30)
Beneficiaries' concern about vaccine's efficacy	19 (15, 22)	0 (0, 1)	18 (15, 22)
The need for beneficiaries to transport the vaccine from a pharmacy to a physician to be administered	8 (5, 12)	1 (1, 2)	7 (4, 11)

Source: GAO 2010 Physician Survey.

Notes: The sampling frame for our survey included practicing family and internal medicine physicians in the United States who were not federal employees and who provided primary care to Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

The sum of the percentages of major/minor barriers may not equal the total percentage due to rounding.

Table 26: Barriers to Stocking, Administering, or Recommending Td/Tdap Vaccines, Reported by Physicians Who Do Not Stock the Vaccines

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Cost of purchasing vaccine stock	70 (55, 85)	47 (32, 62)	23 (10, 36)
Low Medicare reimbursement for the cost and/or administration of the vaccine	93 (89, 98)	72 (57, 87)	21 (7, 36)
Inconsistent Part D plans' coverage and reimbursement rates	89 (82, 96)	68 (52, 84)	21 (6, 36)
The time and effort required to assess beneficiary Medicare coverage for the vaccine and pursue Medicare reimbursement for providing and/or administering the vaccine	87 (78, 96)	65 (51, 79)	22 (7, 36)
Trouble stocking the vaccine due to shortage/order backlog	33 (18, 48)	8 (3, 13)	25 (10, 39)
Storage difficulties (the need to store the vaccine in a refrigerator/freezer)	18 (4, 31)	2 (0, 3)	16 (3, 29)
Physician's concern about vaccine's safety	14 (1, 27)	1 (0, 2)	13 (0, 26)
Physician's concern about vaccine's efficacy	7 (4, 11)	1 (0, 2)	7 (4, 9)
Lack of, or uncertain, beneficiary demand for the vaccine	53 (36, 70)	13 (3, 22)	40 (22, 59)
Beneficiaries' lack of insurance coverage	79 (67, 90)	49 (31, 66)	30 (14, 46)
Beneficiaries' difficulty affording the cost sharing for the vaccine	69 (53, 85)	34 (19, 49)	35 (20, 51)
Beneficiaries' concern about vaccine's safety	39 (21, 56)	2 (0, 3)	37 (20, 54)
Beneficiaries' concern about vaccine's efficacy	33 (16, 49)	2 (0, 3)	31 (14, 47)
The need for beneficiaries to transport the vaccine from a pharmacy to a physician to be administered	42 (23, 60)	14 (1, 27)	28 (11, 44)

Source: GAO 2010 Physician Survey.

Notes: The sampling frame for our survey included practicing family and internal medicine physicians in the United States who were not federal employees and who provided primary care to Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

The sum of the percentages of major/minor barriers may not equal the total percentage due to rounding.

Table 27: Barriers to Stocking, Administering, or Recommending the Pneumococcal Vaccine, Reported by All Physicians

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Cost of purchasing vaccine stock	38 (34, 42)	15 (12, 18)	23 (19, 26)
Low Medicare reimbursement for the cost and/or administration of the vaccine	58 (52, 64)	29 (25, 33)	29 (25, 34)
The time and effort required to assess beneficiary Medicare coverage for the vaccine and pursue Medicare reimbursement for providing and/or administering the vaccine	45 (39, 51)	19 (14, 24)	26 (22, 31)
Trouble stocking the vaccine due to shortage/order backlog	26 (22, 29)	4 (2, 6)	22 (18, 26)
Storage difficulties (the need to store the vaccine in a refrigerator/freezer)	14 (10, 17)	1 (0, 2)	12 (9, 16)
Physician's concern about vaccine's safety	4 (2, 7)	0 (0, 0)	4 (1, 7)
Physician's concern about vaccine's efficacy	7 (3, 10)	1 (0, 1)	6 (3, 9)
Lack of, or uncertain, beneficiary demand for the vaccine	22 (17, 27)	5 (3, 8)	17 (13, 20)
Beneficiaries' concern about vaccine's safety	35 (31, 39)	3 (2, 4)	32 (28, 35)
Beneficiaries' concern about vaccine's efficacy	26 (23, 30)	2 (1, 3)	25 (21, 28)
The need for beneficiaries to transport the vaccine from a pharmacy to a physician to be administered	8 (5, 11)	2 (1, 3)	6 (3, 9)

Source: GAO 2010 Physician Survey.

Notes: The sampling frame for our survey included practicing family and internal medicine physicians in the United States who were not federal employees and who provided primary care to Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

The sum of the percentages of major/minor barriers may not equal the total percentage due to rounding.

Table 28: Barriers to Stocking, Administering, or Recommending the Pneumococcal Vaccine, Reported by Physicians Who Stock the Vaccine

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Cost of purchasing vaccine stock	34 (29, 38)	11 (9, 13)	23 (19, 26)
Low Medicare reimbursement for the cost and/or administration of the vaccine	55 (49, 62)	25 (21, 28)	31 (26, 36)
The time and effort required to assess beneficiary Medicare coverage for the vaccine and pursue Medicare reimbursement for providing and/or administering the vaccine	42 (36, 48)	15 (10, 21)	27 (22, 31)
Trouble stocking the vaccine due to shortage/order backlog	25 (22, 29)	3 (1, 5)	22 (18, 26)
Storage difficulties (the need to store the vaccine in a refrigerator/freezer)	13 (10, 17)	1 (0, 2)	12 (8, 16)
Physician's concern about vaccine's safety	4 (1, 7)	0 (0, 0)	4 (1, 6)
Physician's concern about vaccine's efficacy	6 (2, 10)	1 (0, 1)	5 (2, 9)
Lack of, or uncertain, beneficiary demand for the vaccine	20 (15, 24)	4 (2, 6)	16 (12, 19)
Beneficiaries' concern about vaccine's safety	34 (30, 38)	3 (2, 4)	31 (27, 35)
Beneficiaries' concern about vaccine's efficacy	25 (21, 29)	1 (0, 2)	24 (20, 28)
The need for beneficiaries to transport the vaccine from a pharmacy to a physician to be administered	6 (3, 9)	2 (1, 2)	4 (2, 7)

Source: GAO 2010 Physician Survey.

Notes: The sampling frame for our survey included practicing family and internal medicine physicians in the United States who were not federal employees and who provided primary care to Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

The sum of the percentages of major/minor barriers may not equal the total percentage due to rounding.

Table 29: Barriers to Stocking, Administering, or Recommending the Pneumococcal Vaccine, Reported by Physicians Who Do Not Stock the Vaccine

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Cost of purchasing vaccine stock	90 (79, 100)	67 (54, 79)	23 (12, 34)
Low Medicare reimbursement for the cost and/or administration of the vaccine	93 (87, 100)	81 (69, 92)	13 (4, 22)
The time and effort required to assess beneficiary Medicare coverage for the vaccine and pursue Medicare reimbursement for providing and/or administering the vaccine	77 (58, 97)	55 (38, 72)	23 (11, 34)
Trouble stocking the vaccine due to shortage/order backlog	35 (23, 48)	13 (5, 21)	22 (12, 33)
Storage difficulties (the need to store the vaccine in a refrigerator/freezer)	18 (8, 27)	4 (1, 7)	14 (4, 23)
Physician's concern about vaccine's safety	9 (4, 14)	0 (0, 0)	9 (4, 14)
Physician's concern about vaccine's efficacy	14 (6, 23)	2 (0, 4)	13 (4, 21)
Lack of, or uncertain, beneficiary demand for the vaccine	51 (36, 66)	22 (15, 29)	29 (15, 42)
Beneficiaries' concern about vaccine's safety	44 (24, 64)	2 (0, 6)	41 (23, 60)
Beneficiaries' concern about vaccine's efficacy	41 (22, 61)	9 (0, 20)	33 (20, 45)
The need for beneficiaries to transport the vaccine from a pharmacy to a physician to be administered	35 (15, 54)	6 (0, 12)	29 (10, 47)

Source: GAO 2010 Physician Survey.

Notes: The sampling frame for our survey included practicing family and internal medicine physicians in the United States who were not federal employees and who provided primary care to Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

The sum of the percentages of major/minor barriers may not equal the total percentage due to rounding.

Table 30: Physicians' Awareness and Use of Web-Assisted Billing Systems

	Percentage (lower bound, upper bound)
Use system	11 (8, 15)
Aware of system, but do not use it	14 (10, 17)
Not aware of system	75 (70, 80)

Source: GAO 2010 Physician Survey.

Notes: The sampling frame for our survey included practicing family and internal medicine physicians in the United States who were not federal employees and who provided primary care to Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

Table 31: Physicians' Recommendations to Make It Easier for Physicians to Stock and Administer All Routinely Recommended Vaccines

Recommendations	Percentage (lower bound, upper bound)
If all the vaccines were covered under Part B	86 (83, 89)
Increased reimbursement rates for vaccines and their administration	63 (59, 68)
Decreased beneficiary cost sharing for Part D vaccinations	41 (37, 46)
Consistent Part D reimbursement rates for vaccinations covered under Part D, regardless of Part D plan	38 (31, 44)
Increased beneficiary education and/or awareness of routinely recommended vaccinations	34 (31, 37)
If all the vaccines were covered under Part D	28 (24, 32)

Source: GAO 2010 Physician Survey.

Notes: The sampling frame for our survey included practicing family and internal medicine physicians in the United States who were not federal employees and who provided primary care to Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

Appendix V: Selected Results of the GAO 2010 Pharmacy Survey

This appendix summarizes the results from questions we asked pharmacies on common practices for the Part D-covered shingles and Td/Tdap vaccines and, for comparison, the Part B-covered pneumococcal vaccine. We conducted a national mail and telephone survey of 1,500 pharmacies and weighted the responses to provide nationally representative estimates.

The following tables show selected survey information on pharmacy stocking practices (table 32); barriers to stocking, administering, or recommending the shingles, Td/Tdap, and pneumococcal vaccines (tables 33 through 41); and recommendations to make it easier for pharmacies to stock and administer all routinely recommended vaccines (table 42).

Table 32: Pharmacy Stocking Practices

	Shingles percentage (lower bound, upper bound)	Td/Tdap percentage (lower bound, upper bound)	Pneumococcal percentage (lower bound, upper bound)
Stock the vaccine and administer to patients at our pharmacy	26 (20, 31)	18 (13, 24)	42 (34, 50)
Stock the vaccine, but do not administer the vaccine	7 (4, 10)	2 (1, 3)	1 (1, 2)
Stock the vaccine, and our pharmacy employs and/or contracts with medical professionals to administer the vaccine at our pharmacy	2 (2, 2)	1 (1, 2)	3 (2, 3)
Refer beneficiaries to the Public Health Department, and the vaccine is obtained and administered at the Public Health Department	4 (0, 9)	6 (3, 9)	6 (1, 10)
Refer beneficiaries to a physician clinic or practice, and the vaccine is obtained and administered there	40 (34, 46)	60 (54, 67)	40 (35, 45)
Refer beneficiaries to another pharmacy to obtain the vaccine	18 (15, 21)	7 (5, 8)	6 (5, 7)
Other	3 (2, 4)	6 (2, 10)	3 (2, 4)

Source: GAO 2010 Pharmacy Survey.

Notes: The sampling frame for our survey included pharmacies in the United States that were not operated by a federal agency and that served Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

Percentages may not total to 100 percent due to rounding.

Table 33: Barriers to Stocking, Administering, or Recommending the Shingles Vaccine, Reported by All Pharmacies

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Cost of purchasing vaccine stock	42 (32, 53)	19 (11, 26)	23 (16, 31)
Low Medicare reimbursement for the cost and/or administration of the vaccine	53 (43, 64)	21 (11, 30)	33 (26, 40)
Inconsistent Part D plans' coverage and reimbursement rates	71 (68, 74)	42 (33, 50)	29 (21, 37)
The time and effort required to assess beneficiary Medicare coverage for the vaccine and pursue Medicare reimbursement for providing and/or administering the vaccine	51 (42, 60)	31 (23, 40)	20 (15, 24)
Trouble stocking the vaccine due to shortage/order backlog	64 (54, 75)	47 (35, 58)	17 (14, 21)
Storage difficulties (the need to store the vaccine in a refrigerator/freezer)	45 (36, 54)	35 (23, 47)	10 (3, 18)
State statutes/regulations do not allow pharmacist administration of the vaccine	19 (11, 28)	12 (4, 20)	7 (5, 9)
Pharmacy's concern about vaccine's safety	10 (4, 17)	1 (0, 2)	10 (3, 16)
Pharmacy's concern about vaccine's efficacy	11 (4, 19)	1 (0, 3)	10 (3, 18)
Lack of, or uncertain, beneficiary demand for the vaccine	50 (38, 61)	23 (11, 35)	27 (23, 30)
Beneficiaries' lack of insurance coverage	59 (56, 62)	28 (19, 37)	31 (23, 40)
Beneficiaries' difficulty affording the cost sharing for the vaccine	68 (64, 72)	33 (24, 42)	35 (26, 43)
Beneficiaries' concern about vaccine's safety	33 (24, 41)	6 (0, 15)	27 (15, 38)
Beneficiaries' concern about vaccine's efficacy	38 (30, 46)	6 (0, 14)	32 (21, 42)
The need for beneficiaries to transport the vaccine from a pharmacy to a physician to be administered	43 (34, 52)	24 (12, 35)	20 (12, 27)

Source: GAO 2010 Pharmacy Survey.

Notes: The sampling frame for our survey included pharmacies in the United States that were not operated by a federal agency and that served Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

The sum of the percentages of major/minor barriers may not equal the total percentage due to rounding.

Table 34: Barriers to Stocking, Administering, or Recommending the Shingles Vaccine, Reported by Pharmacies That Stock the Vaccine

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Cost of purchasing vaccine stock	34 (26, 41)	11 (8, 15)	23 (13, 32)
Low Medicare reimbursement for the cost and/or administration of the vaccine	58 (51, 65)	21 (11, 31)	37 (31, 44)
Inconsistent Part D plans' coverage and reimbursement rates	78 (74, 81)	38 (31, 46)	39 (33, 45)
The time and effort required to assess beneficiary Medicare coverage for the vaccine and pursue Medicare reimbursement for providing and/or administering the vaccine	43 (35, 52)	16 (7, 25)	28 (19, 36)
Trouble stocking the vaccine due to shortage/order backlog	84 (80, 87)	56 (48, 65)	28 (21, 35)
Storage difficulties (the need to store the vaccine in a refrigerator/freezer)	16 (11, 20)	5 (2, 8)	11 (7, 14)
State statutes/regulations do not allow pharmacist administration of the vaccine	19 (12, 26)	7 (2, 13)	12 (8, 16)
Pharmacy's concern about vaccine's safety	3 (1, 6)	0 (0, 0)	3 (1, 6)
Pharmacy's concern about vaccine's efficacy	6 (3, 9)	0 (0, 0)	6 (3, 9)
Lack of, or uncertain, beneficiary demand for the vaccine	40 (31, 49)	10 (0, 20)	30 (24, 35)
Beneficiaries' lack of insurance coverage	60 (54, 65)	28 (18, 38)	31 (24, 38)
Beneficiaries' difficulty affording the cost sharing for the vaccine	67 (62, 72)	34 (26, 42)	33 (28, 38)
Beneficiaries' concern about vaccine's safety	27 (22, 33)	2 (2, 2)	25 (20, 31)
Beneficiaries' concern about vaccine's efficacy	31 (25, 36)	2 (2, 2)	29 (23, 34)
The need for beneficiaries to transport the vaccine from a pharmacy to a physician to be administered	27 (22, 32)	7 (3, 11)	20 (16, 24)

Source: GAO 2010 Pharmacy Survey.

Notes: The sampling frame for our survey included pharmacies in the United States that were not operated by a federal agency and that served Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

The sum of the percentages of major/minor barriers may not equal the total percentage due to rounding.

Table 35: Barriers to Stocking, Administering, or Recommending the Shingles Vaccine, Reported by Pharmacies That Do Not Stock the Vaccine

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Cost of purchasing vaccine stock	49 (30, 69)	25 (11, 39)	24 (12, 36)
Low Medicare reimbursement for the cost and/or administration of the vaccine	49 (30, 69)	21 (6, 35)	29 (16, 41)
Inconsistent Part D plans' coverage and reimbursement rates	65 (61, 70)	45 (30, 60)	20 (6, 34)
The time and effort required to assess beneficiary Medicare coverage for the vaccine and pursue Medicare reimbursement for providing and/or administering the vaccine	58 (44, 72)	45 (31, 58)	13 (9, 17)
Trouble stocking the vaccine due to shortage/order backlog	47 (27, 68)	39 (20, 58)	8 (5, 12)
Storage difficulties (the need to store the vaccine in a refrigerator/freezer)	69 (54, 83)	59 (39, 78)	10 (0, 23)
State statutes/regulations do not allow pharmacist administration of the vaccine	19 (8, 31)	16 (6, 26)	3 (1, 6)
Pharmacy's concern about vaccine's safety	16 (4, 29)	2 (0, 4)	15 (3, 27)
Pharmacy's concern about vaccine's efficacy	16 (3, 28)	2 (0, 4)	14 (2, 25)
Lack of, or uncertain, beneficiary demand for the vaccine	57 (38, 76)	33 (14, 52)	24 (20, 28)
Beneficiaries' lack of insurance coverage	59 (55, 62)	27 (13, 42)	31 (16, 46)
Beneficiaries' difficulty affording the cost sharing for the vaccine	69 (64, 74)	33 (18, 48)	37 (22, 51)
Beneficiaries' concern about vaccine's safety	37 (22, 53)	10 (0, 26)	27 (8, 47)
Beneficiaries' concern about vaccine's efficacy	43 (29, 58)	9 (0, 24)	34 (16, 52)
The need for beneficiaries to transport the vaccine from a pharmacy to a physician to be administered	56 (42, 70)	37 (18, 56)	19 (6, 33)

Source: GAO 2010 Pharmacy Survey.

Notes: The sampling frame for our survey included pharmacies in the United States that were not operated by a federal agency and that served Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

The sum of the percentages of major/minor barriers may not equal the total percentage due to rounding.

Table 36: Barriers to Stocking, Administering, or Recommending the Td/Tdap Vaccines, Reported by All Pharmacies

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Cost of purchasing vaccine stock	20 (12, 29)	10 (2, 18)	10 (7, 13)
Low Medicare reimbursement for the cost and/or administration of the vaccine	51 (46, 57)	21 (11, 32)	30 (21, 39)
Inconsistent Part D plans' coverage and reimbursement rates	61 (54, 68)	36 (31, 41)	25 (21, 30)
The time and effort required to assess beneficiary Medicare coverage for the vaccine and pursue Medicare reimbursement for providing and/or administering the vaccine	53 (46, 60)	30 (24, 37)	23 (20, 25)
Trouble stocking the vaccine due to shortage/order backlog	30 (23, 38)	10 (1, 18)	21 (9, 32)
Storage difficulties (the need to store the vaccine in a refrigerator/freezer)	25 (20, 31)	12 (2, 22)	14 (5, 22)
State statutes/regulations do not allow pharmacist administration of the vaccine	23 (15, 31)	20 (13, 27)	3 (2, 5)
Pharmacy's concern about vaccine's safety	7 (5, 9)	1 (0, 3)	6 (5, 7)
Pharmacy's concern about vaccine's efficacy	7 (5, 10)	1 (0, 3)	6 (5, 8)
Lack of, or uncertain, beneficiary demand for the vaccine	58 (47, 70)	31 (22, 40)	27 (20, 34)
Beneficiaries' lack of insurance coverage	52 (46, 57)	27 (19, 35)	24 (20, 28)
Beneficiaries' difficulty affording the cost sharing for the vaccine	58 (52, 64)	33 (24, 42)	25 (20, 31)
Beneficiaries' concern about vaccine's safety	27 (15, 39)	9 (0, 18)	18 (9, 27)
Beneficiaries' concern about vaccine's efficacy	27 (16, 38)	8 (0, 17)	19 (10, 27)
The need for beneficiaries to transport the vaccine from a pharmacy to a physician to be administered	23 (14, 32)	6 (2, 10)	17 (9, 26)

Source: GAO 2010 Pharmacy Survey.

Notes: The sampling frame for our survey included pharmacies in the United States that were not operated by a federal agency and that served Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

The sum of the percentages of major/minor barriers may not equal the total percentage due to rounding.

Table 37: Barriers to Stocking, Administering, or Recommending the Td/Tdap Vaccines, Reported by Pharmacies That Stock the Vaccines

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Cost of purchasing vaccine stock	11 (7, 15)	2 (0, 3)	9 (5, 13)
Low Medicare reimbursement for the cost and/or administration of the vaccine	46 (36, 56)	19 (3, 35)	27 (19, 34)
Inconsistent Part D plans' coverage and reimbursement rates	59 (51, 67)	30 (16, 43)	29 (20, 38)
The time and effort required to assess beneficiary Medicare coverage for the vaccine and pursue Medicare reimbursement for providing and/or administering the vaccine	44 (31, 56)	19 (4, 33)	25 (18, 32)
Trouble stocking the vaccine due to shortage/order backlog	5 (3, 7)	0 (0, 1)	5 (3, 7)
Storage difficulties (the need to store the vaccine in a refrigerator/freezer)	1 (0, 2)	0 (0, 0)	1 (0, 2)
State statutes/regulations do not allow pharmacist administration of the vaccine	7 (3, 10)	6 (2, 10)	1 (0, 2)
Pharmacy's concern about vaccine's safety	1 (0, 2)	0 (0, 0)	1 (0, 2)
Pharmacy's concern about vaccine's efficacy	2 (0, 4)	0 (0, 0)	2 (0, 4)
Lack of, or uncertain, beneficiary demand for the vaccine	43 (33, 52)	8 (6, 11)	34 (24, 45)
Beneficiaries' lack of insurance coverage	53 (48, 59)	13 (8, 18)	41 (36, 45)
Beneficiaries' difficulty affording the cost sharing for the vaccine	58 (49, 67)	24 (9, 39)	34 (24, 44)
Beneficiaries' concern about vaccine's safety	9 (6, 12)	0 (0, 0)	9 (6, 12)
Beneficiaries' concern about vaccine's efficacy	9 (6, 12)	0 (0, 0)	9 (6, 12)
The need for beneficiaries to transport the vaccine from a pharmacy to a physician to be administered	12 (7, 18)	7 (2, 12)	6 (4, 7)

Source: GAO 2010 Pharmacy Survey.

Notes: The sampling frame for our survey included pharmacies in the United States that were not operated by a federal agency and that served Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

The sum of the percentages of major/minor barriers may not equal the total percentage due to rounding.

Table 38: Barriers to Stocking, Administering, or Recommending the Td/Tdap Vaccines, Reported by Pharmacies That Do Not Stock the Vaccines

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Cost of purchasing vaccine stock	25 (12, 38)	14 (2, 27)	11 (6, 15)
Low Medicare reimbursement for the cost and/or administration of the vaccine	54 (45, 62)	22 (9, 36)	31 (18, 45)
Inconsistent Part D plans' coverage and reimbursement rates	62 (53, 71)	39 (32, 45)	24 (19, 28)
The time and effort required to assess beneficiary Medicare coverage for the vaccine and pursue Medicare reimbursement for providing and/or administering the vaccine	57 (49, 66)	36 (29, 43)	21 (17, 25)
Trouble stocking the vaccine due to shortage/order backlog	42 (33, 51)	14 (1, 27)	28 (12, 44)
Storage difficulties (the need to store the vaccine in a refrigerator/freezer)	37 (30, 44)	17 (3, 31)	20 (7, 32)
State statutes/regulations do not allow pharmacist administration of the vaccine	30 (20, 40)	26 (16, 35)	5 (3, 7)
Pharmacy's concern about vaccine's safety	10 (7, 13)	2 (0, 4)	9 (7, 10)
Pharmacy's concern about vaccine's efficacy	10 (7, 13)	2 (0, 4)	8 (7, 10)
Lack of, or uncertain, beneficiary demand for the vaccine	64 (49, 79)	40 (27, 53)	24 (15, 34)
Beneficiaries' lack of insurance coverage	51 (44, 58)	34 (23, 44)	17 (13, 21)
Beneficiaries' difficulty affording the cost sharing for the vaccine	58 (51, 65)	37 (27, 46)	21 (16, 27)
Beneficiaries' concern about vaccine's safety	36 (19, 53)	13 (0, 26)	23 (9, 37)
Beneficiaries' concern about vaccine's efficacy	36 (20, 51)	12 (0, 25)	24 (11, 36)
The need for beneficiaries to transport the vaccine from a pharmacy to a physician to be administered	28 (15, 40)	5 (0, 11)	22 (10, 35)

Source: GAO 2010 Pharmacy Survey.

Notes: The sampling frame for our survey included pharmacies in the United States that were not operated by a federal agency and that served Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

The sum of the percentages of major/minor barriers may not equal the total percentage due to rounding.

Table 39: Barriers to Stocking, Administering, or Recommending the Pneumococcal Vaccine, Reported by All Pharmacies

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Cost of purchasing vaccine stock	20 (12, 28)	8 (1, 15)	12 (9, 14)
Low Medicare reimbursement for the cost and/or administration of the vaccine	46 (43, 50)	17 (9, 26)	29 (21, 36)
The time and effort required to assess beneficiary Medicare coverage for the vaccine and pursue Medicare reimbursement for providing and/or administering the vaccine	53 (46, 60)	32 (24, 39)	21 (19, 23)
Trouble stocking the vaccine due to shortage/order backlog	33 (24, 42)	8 (1, 16)	24 (19, 29)
Storage difficulties (the need to store the vaccine in a refrigerator/freezer)	23 (16, 31)	9 (0, 17)	15 (6, 24)
State statutes/regulations do not allow pharmacist administration of the vaccine	18 (10, 26)	8 (2, 15)	10 (7, 12)
Pharmacy's concern about vaccine's safety	9 (3, 15)	1 (0, 2)	8 (2, 15)
Pharmacy's concern about vaccine's efficacy	8 (2, 13)	0 (0, 0)	8 (2, 13)
Lack of, or uncertain, beneficiary demand for the vaccine	67 (61, 72)	27 (18, 36)	40 (32, 47)
Beneficiaries' concern about vaccine's safety	35 (32, 39)	5 (0, 13)	30 (22, 37)
Beneficiaries' concern about vaccine's efficacy	35 (32, 38)	6 (0, 13)	29 (22, 36)
The need for beneficiaries to transport the vaccine from a pharmacy to a physician to be administered	24 (13, 34)	5 (3, 7)	19 (9, 28)

Source: GAO 2010 Pharmacy Survey.

Notes: The sampling frame for our survey included pharmacies in the United States that were not operated by a federal agency and that served Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

The sum of the percentages of major/minor barriers may not equal the total percentage due to rounding.

Table 40: Barriers to Stocking, Administering, or Recommending the Pneumococcal Vaccine, Reported by Pharmacies That Stock the Vaccine

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Cost of purchasing vaccine stock	7 (4, 9)	1 (0, 1)	6 (4, 8)
Low Medicare reimbursement for the cost and/or administration of the vaccine	36 (29, 43)	11 (4, 18)	25 (19, 30)
The time and effort required to assess beneficiary Medicare coverage for the vaccine and pursue Medicare reimbursement for providing and/or administering the vaccine	37 (30, 44)	14 (8, 21)	22 (19, 26)
Trouble stocking the vaccine due to shortage/order backlog	25 (13, 36)	1 (0, 2)	23 (12, 35)
Storage difficulties (the need to store the vaccine in a refrigerator/freezer)	8 (6, 11)	2 (0, 4)	6 (5, 8)
State statutes/regulations do not allow pharmacist administration of the vaccine	11 (7, 15)	3 (0, 6)	8 (6, 10)
Pharmacy's concern about vaccine's safety	3 (1, 4)	1 (0, 2)	1 (1, 2)
Pharmacy's concern about vaccine's efficacy	2 (1, 3)	0 (0, 0)	2 (1, 3)
Lack of, or uncertain, beneficiary demand for the vaccine	55 (45, 64)	20 (12, 28)	35 (24, 45)
Beneficiaries' concern about vaccine's safety	27 (18, 35)	6 (0, 18)	21 (16, 25)
Beneficiaries' concern about vaccine's efficacy	26 (18, 35)	6 (0, 18)	20 (15, 25)
The need for beneficiaries to transport the vaccine from a pharmacy to a physician to be administered	13 (10, 16)	3 (1, 6)	10 (7, 12)

Source: GAO 2010 Pharmacy Survey.

Notes: The sampling frame for our survey included pharmacies in the United States that were not operated by a federal agency and that served Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

The sum of the percentages of major/minor barriers may not equal the total percentage due to rounding.

Table 41: Barriers to Stocking, Administering, or Recommending the Pneumococcal Vaccine, Reported by Pharmacies That Do Not Stock the Vaccine

Barrier	Total percentage (lower bound, upper bound)	Major barrier percentage (lower bound, upper bound)	Minor barrier percentage (lower bound, upper bound)
Cost of purchasing vaccine stock	38 (20, 56)	19 (3, 34)	20 (14, 25)
Low Medicare reimbursement for the cost and/or administration of the vaccine	62 (53, 70)	27 (9, 44)	35 (18, 52)
The time and effort required to assess beneficiary Medicare coverage for the vaccine and pursue Medicare reimbursement for providing and/or administering the vaccine	74 (70, 79)	56 (49, 62)	19 (14, 23)
Trouble stocking the vaccine due to shortage/order backlog	44 (25, 63)	18 (1, 35)	26 (14, 37)
Storage difficulties (the need to store the vaccine in a refrigerator/freezer)	46 (37, 56)	18 (0, 38)	28 (8, 48)
State statutes/regulations do not allow pharmacist administration of the vaccine	27 (14, 41)	16 (5, 26)	12 (8, 16)
Pharmacy's concern about vaccine's safety	19 (7, 31)	0 (0, 0)	19 (7, 31)
Pharmacy's concern about vaccine's efficacy	16 (5, 28)	0 (0, 0)	16 (5, 28)
Lack of, or uncertain, beneficiary demand for the vaccine	83 (79, 87)	37 (18, 55)	46 (28, 64)
Beneficiaries' concern about vaccine's safety	48 (40, 56)	4 (2, 7)	44 (35, 52)
Beneficiaries' concern about vaccine's efficacy	48 (40, 56)	5 (3, 8)	43 (33, 52)
The need for beneficiaries to transport the vaccine from a pharmacy to a physician to be administered	39 (19, 59)	7 (3, 11)	32 (12, 52)

Source: GAO 2010 Pharmacy Survey.

Notes: The sampling frame for our survey included pharmacies in the United States that were not operated by a federal agency and that served Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

The sum of the percentages of major/minor barriers may not equal the total percentage due to rounding.

Table 42: Pharmacies' Recommendations to Make It Easier for Pharmacies to Stock and Administer All Routinely Recommended Vaccines

Recommendations	Percentage (lower bound, upper bound)
If all the vaccines were covered under Part B	30 (24, 36)
If all the vaccines were covered under Part D	69 (63, 75)
Consistent Part D reimbursement rates for vaccinations covered under Part D, regardless of Part D plan	52 (44, 59)
Increased beneficiary education and/or awareness of routinely recommended vaccinations	43 (36, 50)
Decreased beneficiary cost sharing for Part D vaccinations	29 (24, 34)
Increased reimbursement rates for vaccines and their administration	49 (41, 58)

Source: GAO 2010 Pharmacy Survey.

Notes: The sampling frame for our survey included pharmacies in the United States that were not operated by a federal agency and that served Medicare beneficiaries age 65 and older.

Lower and upper bounds display 95 percent confidence levels for estimates.

Appendix VI: State Health Insurance Assistance Program Survey Results

This appendix summarizes the results from questions we asked SHIPs—state agencies that provide counseling and assistance to Medicare beneficiaries. We conducted a web-based survey of all 51 state SHIPs, including the District of Columbia, to obtain information on beneficiary questions and concerns related to vaccinations covered under Part D, specifically the shingles and Td/Tdap vaccinations. For comparison, we also asked about the Part B-covered pneumococcal vaccination. We obtained responses from all 51 SHIPs.

The following tables show selected survey information on the number of SHIPs helping beneficiaries understand Medicare vaccination coverage (table 43); reporting beneficiary difficulties accessing shingles, Td/Tdap, or pneumococcal vaccinations (tables 44 through 46); and making recommendations to improve beneficiaries' access to routinely recommended vaccinations (table 47).

Table 43: Number of SHIPs Helping Beneficiaries Understand Medicare Vaccination Coverage

Beneficiaries' coverage issue	Number of SHIPs
Whether a vaccination is covered by Medicare Part B or D	47
Cost-sharing amount for a Part D-covered vaccination	38
How to obtain reimbursement for a Part D-covered vaccination	33
Up-front costs when beneficiaries have to pursue reimbursement themselves	30

Source: GAO 2010 SHIP Survey.

Table 44: Number of SHIPs Reporting Beneficiary Difficulties Accessing Shingles Vaccinations

Beneficiary difficulties	Number of SHIPs
Do not know whether vaccination is covered by Medicare	36
Concerns about having to transport the vaccine from a pharmacy to a physician to be administered	24
Difficulty affording the cost sharing for vaccination	20
Physician does not stock the vaccine	19
Difficulty affording up-front costs of vaccination when responsible for pursuing reimbursement	18
Pharmacy does not administer the vaccine	17
Difficulty pursuing reimbursement for vaccination	14
Pharmacy does not stock the vaccine	10
Do not have Part D or other insurance coverage for vaccination	10
Physician does not administer the vaccine	9

Source: GAO 2010 SHIP Survey.

Table 45: Number of SHIPs Reporting Beneficiary Difficulties Accessing Td/Tdap Vaccinations

Beneficiary difficulties	Number of SHIPs
Do not know whether vaccination is covered by Medicare	16
Pharmacy does not stock the vaccine	3
Concerns about having to transport the vaccine from a pharmacy to a physician to be administered	3
Do not have Part D or other insurance coverage for vaccination	3
Difficulty pursuing reimbursement for vaccination	3
Physician does not administer the vaccine	2
Difficulty affording the cost sharing for vaccination	2
Difficulty affording up front costs of vaccination when responsible for pursuing reimbursement	2
Pharmacy does not administer the vaccine	1
Physician does not stock the vaccine	0

Source: GAO 2010 SHIP Survey.

Table 46: Number of SHIPs Reporting Beneficiary Difficulties Accessing Pneumococcal Vaccinations

Beneficiary difficulties	Number of SHIPs
Do not know whether vaccination is covered by Medicare	20
Pharmacy does not administer the vaccine	4
Difficulty pursuing reimbursement for vaccination	4
Difficulty affording up-front costs of vaccination when responsible for pursuing reimbursement	3
Physician does not stock the vaccine	2
Physician does not administer the vaccine	2
Pharmacy does not stock the vaccine	2
Concerns about having to transport the vaccine from a pharmacy to a physician to be administered	1

Source: GAO 2010 SHIP Survey.

Table 47: SHIP Recommendations to Improve Beneficiaries' Access to Routinely Recommended Vaccinations

Recommendations	Number of SHIPs
Increased beneficiary education and awareness of routinely recommended vaccinations	42
Coverage of all vaccinations under Part B	39
Consistent Part D cost sharing for vaccinations covered under Part D	29
Decreased beneficiary cost sharing for Part D vaccinations	28
Coverage of all vaccinations under Part D	12

Source: GAO 2010 SHIP Survey.

Appendix VII: Beneficiaries' Part D Cost Sharing for Shingles and Td/Tdap Vaccinations

This appendix presents Medicare data on the amount paid for shingles and Td/Tdap vaccinations by Part D beneficiaries who were not receiving the low-income subsidy (LIS). Beneficiary cost sharing data include any applicable vaccine administration costs and are presented for each of the three Part D coverage phases—initial, coverage gap (donut hole), and catastrophic.[1] In 2009, more than 90 percent of Part D beneficiaries who had a shingles or Td/Tdap vaccination reimbursed by Part D received their vaccination in the initial Part D coverage phase. Part D beneficiaries vaccinated during the initial phase paid, on average, $53 for a shingles vaccination (see table 48) and $25 for a Td/Tdap vaccination (see table 49). Part D beneficiaries vaccinated while in the donut hole generally had higher cost sharing, averaging $151 for a shingles vaccination and $35 for a Td/Tdap vaccination. However, starting on January 1, 2011, a provision in the Patient Protection and Affordable Care Act reduced Part D beneficiaries' cost sharing in the donut hole by 50 percent for applicable drugs, including shingles and Td/Tdap vaccinations.[2]

[1]The standard Part D benefit includes an annual deductible and consists of three phases: (1) an initial phase with coverage up to a specified level of spending, (2) a coverage gap when beneficiaries pay a greater portion of the cost of their drugs, and (3) a catastrophic phase where beneficiary cost sharing is minimal.

[2]This provision phases out the donut hole by 2020, at which time Part D beneficiaries' cost sharing will be 25 percent of the cost of the vaccine until beneficiaries' Part D drug costs reach the catastrophic threshold. *See* Pub. L. No. 111-148, § 3301, 124 Stat. 461 (as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 1101, 124 Stat 1029, 1036).

Table 48: 2009 Cost-Sharing Amounts for Shingles Vaccinations by Phase for Beneficiaries Age 65 and Older with Part D Coverage (Non-LIS)

Phase	Percentage of claims	Average cost sharing	Median cost sharing	Range of cost sharing	Range of cost sharing, 10th to 90th percentile
Initial	95.1	$53	$39	$0-$195	$30-$82
Coverage gap	4.1	$151	$170	$0-$195	$54-$188
Catastrophic	0.8	$13	$9	$0-$190	$8-$11

Source: GAO.

Notes: This table presents analysis of 2009 Medicare Part D data for Part D beneficiaries age 65 and older who were not receiving the LIS, excluding claims from employer plans, religious fraternal benefit plans, CMS demonstrations, and programs of all-inclusive care for the elderly. Cost-sharing amounts include applicable vaccine administration costs.

Table 49: 2009 Cost-Sharing Amounts for Td/Tdap Vaccinations by Phase for Beneficiaries Age 65 and Older with Part D Coverage (Non-LIS)

Phase	Percentage of claims	Average cost sharing	Median cost sharing	Range of cost sharing	Range of cost sharing, 10th to 90th percentile
Initial	96.6	$25	$27	$0-$70	$10-$40
Coverage gap	2.9	$35	$27	$0-$70	$20-$59
Catastrophic	0.4	$9	$6	$0-$59	$0-$37

Source: GAO.

Note: This table presents analysis of 2009 Medicare Part D data for Part D beneficiaries age 65 and older who were not receiving the LIS, excluding claims from employer plans, religious fraternal benefit plans, CMS demonstrations, and programs of all-inclusive care for the elderly. Cost-sharing amounts presented include applicable vaccine administration costs and includes both Td and Tdap vaccinations.

Beneficiaries' average cost sharing for shingles and Td/Tdap vaccinations increased from 2007 through 2009, particularly for Td/Tdap vaccinations (see table 50).

Table 50: Average Cost-Sharing Amounts for Shingles and Td/Tdap Vaccinations for Non-LIS Part D Beneficiaries Age 65 and Older, 2007 through 2009

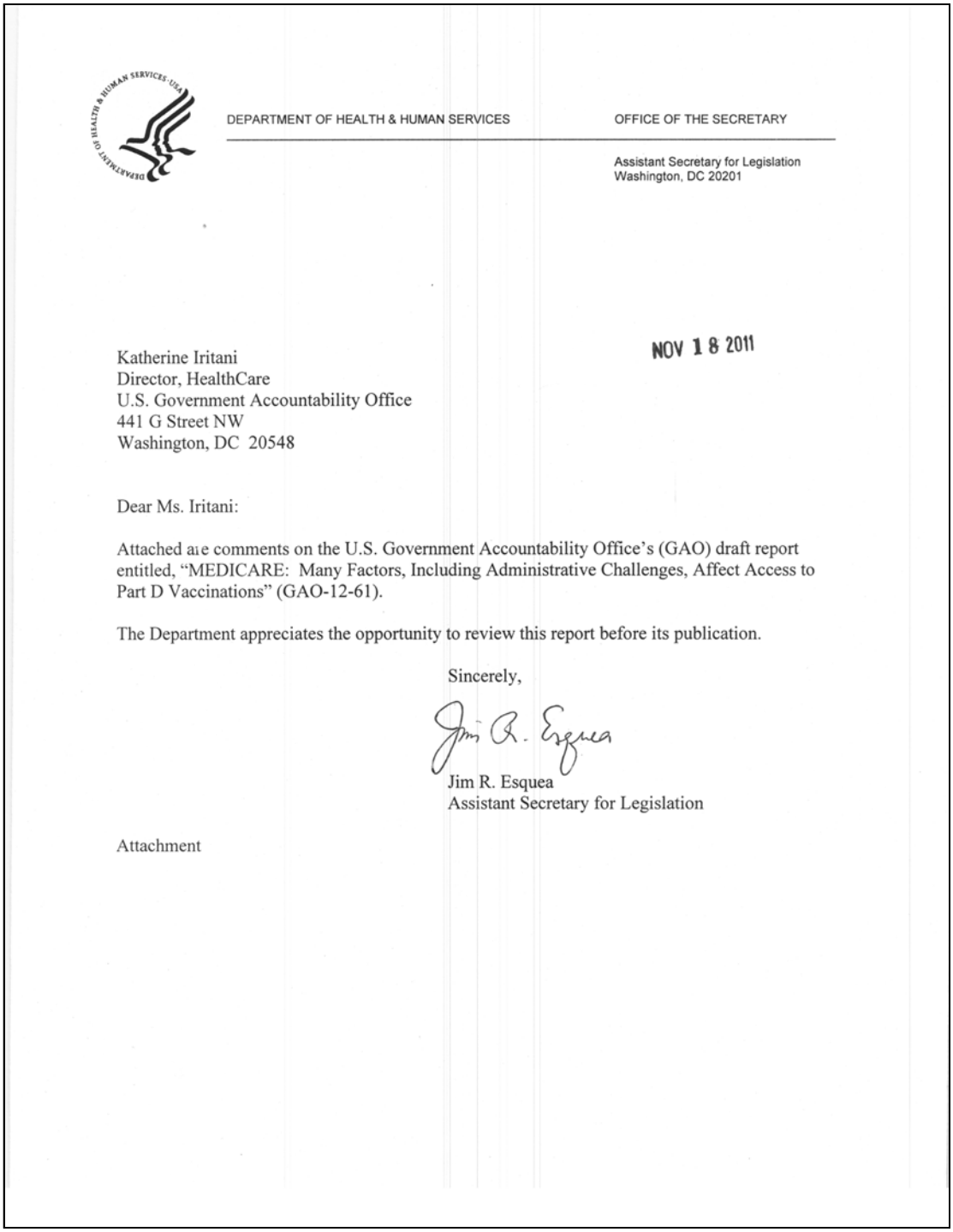
	Average cost sharing		
Vaccine	**2007**	**2008**	**2009**
Shingles	$48	$54	$57
Td/Tdap	$3	$15	$25

Source: GAO.

Notes: This table presents analysis of 2009 Medicare Part D data for Part D beneficiaries age 65 and older who were not receiving the LIS, excluding beneficiaries enrolled in employer plans, religious fraternal benefit plans, CMS demonstrations, and programs of all-inclusive care for the elderly.

Cost-sharing amounts for 2008 and 2009 include payments toward vaccine administration fees. Cost-sharing amounts for 2007 exclude payments toward vaccine administration fees. Prior to 2008, administration fees for Part D-covered vaccines were reimbursed by Part B. Td/Tdap average cost sharing includes both Td and Tdap vaccinations.

Appendix VIII: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES — OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

NOV 18 2011

Katherine Iritani
Director, HealthCare
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Iritani:

Attached are comments on the U.S. Government Accountability Office's (GAO) draft report entitled, "MEDICARE: Many Factors, Including Administrative Challenges, Affect Access to Part D Vaccinations" (GAO-12-61).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

Jim R. Esquea

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "MEDICARE: MANY FACTORS, INCLUDING ADMINISTRATIVE CHALLENGES, AFFECT ACCESS TO PART D VACCINATIONS" (GAO-12-61)

Thank you for the opportunity to review and comment on this draft report. As the report notes, vaccines have the potential to prevent disease and improve the quality of life for individuals enrolled in Medicare, in addition to improving public health in the United States overall. To this end, the Centers for Medicare and Medicaid Services (CMS) has taken steps to improve access to vaccines covered by Part D. All Part D formularies are reviewed to ensure inclusion of licensed vaccines. In addition, for Contract Year 2012, CMS has announced a simplified six tier formulary design that allows Part D plans to have a 6th tier in its benefit design if it is a tier that provides a meaningful benefit offering, such as a $0 vaccine-only tier. The purpose of this policy is to encourage Part D sponsors to offer vaccines at low or no cost and encourage beneficiaries to utilize the vaccination benefit.

GAO Recommendation

To help improve the ability of Medicare beneficiaries to obtain routinely recommended vaccinations, GAO recommend that the Administrator of CMS explore options and take appropriate steps to address administrative challenges, such as physicians' difficulty in verifying beneficiaries' coverage and billing for Part D-covered vaccinations.

CMS Response

We concur with the recommendation for CMS to explore options and take appropriate steps to improve access to Part D covered vaccinations. We agree that a multitude of factors affect beneficiaries' access to routinely recommended Part D-covered vaccinations, particularly the low percentage of physicians and pharmacies that stock the relatively new shingles vaccine. We also agree that a number of stakeholders are involved in ensuring that Medicare beneficiaries have access to routinely recommended vaccinations. As to the administrative challenges associated with the Medicare Part D program in particular, we continue to explore options to increase beneficiary access to vaccines covered by the Part D on top of the guidance that we have already issued which is referenced in the proposed report.

Appendix IX: GAO Contact and Staff Acknowledgments

GAO Contact

Katherine Iritani, (202) 512-7114 or iritanik@gao.gov

Staff Acknowledgments

In addition to the contact named above, Kim Yamane, Assistant Director; George Bogart; Michael Erhardt; Roseanne Price; Terry Saiki; Eden Savino; and Jessica Smith made major contributions to this report.