

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Parts 482, 485, 491, and 494

[CMS–3213–P]

RIN 0938–AP92

### Medicare & Medicaid Programs; Influenza Vaccination Standard for Certain Participating Providers and Suppliers

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would require certain Medicare and Medicaid providers and suppliers to offer all patients an annual influenza vaccination, unless medically contraindicated or unless the patient or patient's representative or surrogate declined vaccination. This proposed rule is intended to increase the number of patients receiving annual vaccination against seasonal influenza and to decrease the morbidity and mortality rates from influenza. This proposed rule would also require certain providers and suppliers to develop policies and procedures that would allow them to offer vaccinations for pandemic influenza, in case of a future pandemic influenza event for which a vaccine may be developed.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. EST on July 5, 2011.

**ADDRESSES:** In commenting, please refer to file code CMS–3213–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3213–P, P.O. Box 8010, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the

following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3213–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

*Submission of comments on paperwork requirements.* You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document. For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Lauren Oviatt, (410) 786–4683. Maria Hammel, (410) 786–1775. Jeannie Miller, (410) 786–3164.

#### **SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have

been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

### I. Background

#### A. General Overview

Various sections of the Social Security Act (the Act) define the terms that Medicare uses for each provider and supplier's regulatory provisions. In some cases, these definitions describe the requirements providers and suppliers must meet for purposes of the Medicare program. Generally, these provisions also specify that the Secretary of the Department of Health and Human Services (HHS) (the Secretary) may establish such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals receiving services.

The Secretary has established in regulations the requirements that each provider and supplier must meet to participate in the Medicare and Medicaid programs. These requirements are called the Conditions of Participation (CoPs) for providers and the Conditions for Coverage or Conditions for Certification (CfCs) for certain suppliers. The CoPs and CfCs are intended to protect public health and safety and to ensure that high quality care is provided to all persons.

To help reduce the spread of seasonal influenza infection, we are proposing to establish influenza vaccination standards for the following providers and suppliers:

- Hospitals (all types that participate in Medicare)
- Critical Access Hospitals (CAHs)
- Rural Health Clinics (RHCs)
- Federally Qualified Health Centers (FQHCs)
- End-Stage Renal Disease (ESRD) Facilities

These providers and suppliers have in common two key factors: (1) In each setting, the patients present before health care providers with staff licensed to provide vaccination at the time and location of the encounter; and (2) all have ready access to equipment and

storage appropriate for handling, controlling, and administering vaccines.

### B. *The Impact of Influenza*

Influenza and pneumococcal disease kill more people in the United States (U.S.) each year than all other vaccine-preventable diseases combined.

Influenza and pneumonia combined represent the fifth leading cause of death in the elderly. Influenza infection rates are highest among children, yet rates of serious illness and death are highest among persons age 65 or older and persons of any age who have medical conditions that place them at increased risk for complications from influenza (See Centers for Disease Control (CDC), "Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP)", MMWR 2008; 57(RR-7): 1-60).

The estimated number of annual influenza-associated deaths from respiratory and circulatory causes (including pneumonia and influenza causes) during 1976 through 2007, ranged from 3,349 in 1986 through 1987 to 48,614 in 2003 through 2004. An average of 220,000 influenza-associated hospitalizations occurred during seasonal influenza epidemics over the same time period. Ninety percent of the influenza related deaths occur in the 65 years and older age group. When combined with underlying medical conditions, this group's estimated risk of influenza-associated hospitalizations is 560 per 100,000 persons, compared with 190 per 100,000 healthy elderly persons. Among persons age 50 to 64, the risk for influenza-associated hospitalizations is also substantially higher for persons with underlying conditions compared with healthy adults. (See CDC, "Estimates of Death Associated With Seasonal Influenza—United States, 1976–2007," MMWR 2010; 59(33):1057–1062; and CDC, "Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)", MMWR 2009; 58(RR-8): 1–56).

The economic cost to society for seasonal influenza has been estimated to be \$87.1 billion each year, including \$10.4 billion in direct medical costs (See Molinari NA, Ortega-Sanchez JR, Messonnier ML, *et al.*, "The annual impact of seasonal influenza in the US: Measuring disease burden and costs," Vaccine 2007; 25: 5086–96).

### C. *Influenza Prevention Through Vaccination*

Influenza vaccination is the primary method for preventing influenza and its

more severe complications. According to the ACIP, influenza vaccination should be provided to all persons 6 months of age and older (CDC, "Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)", MMWR 2010; 59 (RR-8): 1–62). While certain groups are at higher risk for influenza infection or complications (including infants younger than 6 months and children from ages 6 months to 18 years old, pregnant women, persons age 50 or older, and adults with certain chronic medical conditions), vaccination can offer protection to all individuals. However, less than 40 percent of the population received an influenza vaccination during the 2008 to 2009 influenza season. (See CDC, "Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)", MMWR 2009; 58(RR-8): 1–56).

Vaccination has been shown to reduce influenza illness, work absenteeism, antibiotic use, physician visits, hospitalization, and deaths. An ACIP report states that, "vaccination is associated with reductions in influenza-related respiratory illness and physician visits among all age groups, hospitalization and death among persons at high risk, otitis media (ear infections) among children, and work absenteeism among adults" (See MMWR, "Recommendations and Reports", May 28, 2004/53(RR06); 1–40).

Although influenza vaccination levels increased substantially during the 1990s, further improvements in vaccine coverage levels are needed. The Healthy People 2010 target for influenza vaccination among persons age 65 or older was 90 percent and the Healthy People 2020 target for this population continues at 90 percent (IID 12.7 at <http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicid=23>). The national influenza vaccination coverage for the 2006 to 2007 influenza season among persons age 65 or older was estimated to be only 66.8 percent (National Health Interview Survey, 2007, [http://www.cdc.gov/nchs/data/nhis/earlyrelease/200806\\_04.pdf](http://www.cdc.gov/nchs/data/nhis/earlyrelease/200806_04.pdf)).

We believe that there are missed opportunities for vaccinating persons, especially those at higher risk for influenza complications, including opportunities to vaccinate patients who are in the hospital for other causes. In a national study of Medicare patients (who are primarily elderly or disabled) hospitalized with common clinical conditions, a large proportion had not

received influenza vaccination before hospitalization and very few received vaccination while in the hospital (See Bratzler DW, Houck PM, Jiang H, *et al.*, "Failure to vaccinate Medicare inpatients: A missed opportunity", Arch Intern Med 2002; 162: 2349–56).

Although the success of childhood vaccination programs has resulted in the reduction or elimination of vaccine-preventable diseases among children, similar success has not been attained among adults (See Roush SW, Murphy TV, "Historical Comparisons of Morbidity and Mortality for Vaccine-Preventable Diseases in the U.S.", JAMA 2007; 298(18): 2155–2163).

We have made previous efforts to increase vaccination. For example, Section 4107 of the Balanced Budget Act of 1997 extended the influenza and pneumococcal vaccination campaign conducted by the Centers for Medicare & Medicaid Services (CMS) in conjunction with CDC and the National Coalition for Adult Immunization (NCAI) through fiscal year 2002, authorizing \$8 million for each fiscal year from 1998 to 2002. Although Medicare coverage of influenza vaccine was increased under this legislation, rates of vaccination did not improve as anticipated.

On October 2, 2002, we published a final rule with comment period entitled, "Condition of Participation: Immunization Standards for Hospitals, Long-Term Care Facilities, and Home Health Agencies" (67 FR 61808) that removed the patient-specific physician order requirement for the administration of influenza and pneumococcal vaccines from the CoPs for Medicare and Medicaid participating hospitals, LTC facilities, and home health agencies (HHAs). The final rule was effective as of its October 2, 2002 publication date. These vaccines can now be administered per a physician approved facility or agency policy, following assessment of the patient or resident for contraindications. On October 7, 2005, we published a final rule entitled, "Condition of Participation: Immunization Standard for Long Term Care Facilities" (70 FR 58834) that requires participating nursing homes to offer all residents an annual influenza vaccination. This final rule was a major step towards increasing the vaccination rates in the LTC population, as the vaccination rate reached 90 percent in the first year the rule was effective (beginning October 7, 2005, per the Current Medicare Beneficiary Survey). More recent data from the Minimum Data Set shows that the national average for influenza vaccinations administered to LTC residents is approximately 91

percent (data period October 1, 2008 through March 31, 2010).

Other strategies for increasing rates of influenza vaccination include physician reminders (for example, flagging charts) and patient reminders (CDC, MMWR 2008; 57(RR-7): 1-60). In February 2010, the ACIP expanded its previous vaccination recommendations to include all adults beginning in the 2010 through 2011 influenza season. That is, the ACIP now recommends that all people age 6 months and older receive annual influenza vaccinations (CDC, "Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)", MMWR 2010; 59 (RR-8): 1-62).

Until this year, ACIP recommendations endorsed by the CDC (hereafter referred to as ACIP recommendations) for seasonal influenza vaccination focused on vaccination of higher risk adults, children ages 6 months to 18 years, and persons with close contact with people of higher risk. These recommendations applied to about 85 percent of the U.S. population. However, the ACIP is now focusing its attention on protecting all people, including healthy persons aged 6 months and older, who were hard hit by the 2009 H1N1 pandemic virus, which has continued circulating into this season and may continue beyond. Previously the ACIP did not specifically recommend vaccination for healthy adults between the ages of 19 and 49.

Another reason cited in favor of a universal recommendation for vaccination is that many people in currently recommended "higher risk" groups are unaware that they are considered at risk and recommended for vaccination. The ACIP also recognizes the practicality and value of issuing a simple and clear message regarding the importance of influenza vaccination in the hopes that this would remove impediments to vaccination and expand coverage.

Finally, new data collected over the course of the 2009 H1N1 pandemic indicates that some people who did not previously have a specific recommendation for vaccination may also be at higher risk of serious influenza-related complications, including those people who are obese, post-partum women, and people in certain racial/ethnic groups (<http://www.cdc.gov/media/pressrel/2010/r100224.htm> and CDC, "Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)", MMWR 2010; 59 (RR-8): 1-62).

#### D. Pandemic Influenza

A pandemic is the worldwide spread of a new disease. An influenza pandemic occurs when a new influenza virus emerges and spreads around the world, and most people do not have immunity. Viruses that have caused past pandemics typically originated from animal influenza viruses.

This dynamic nature of influenza viruses creates the possibility that a new virus will develop, either through mutation or mixing of individual influenza viruses, in turn creating the possibility for new viral strains that can cause illness and spread efficiently among humans. When a pandemic virus strain emerges, 25 to 35 percent of the population could develop clinical disease, increasing their risk of mortality. The direct and indirect health costs alone (not including disruptions in trade and other costs to business and industry) have been estimated to approach \$181 billion for a moderate pandemic (similar to those in 1957 and 1968) with no interventions. Faced with the threat of a severe pandemic, the U.S. and its international partners will need to respond quickly and forcefully to reduce the spread of influenza and lessen the number of severe illnesses and deaths and the burden on the healthcare system. HHS has developed the *HHS Pandemic Influenza Plan* specifically to prepare for responding to a severe pandemic (see <http://www.hhs.gov/pandemicflu/plan/part1.html>).

In April 2009, a new influenza A (H1N1) virus was determined to be the cause of influenza illness in two children in the United States during March and April 2009 and the cause of outbreaks of respiratory illness in Mexico. This virus was transmitted in communities across North America within weeks and was identified in many areas of the world by May 2009. On June 11, 2009, the World Health Organization (WHO) declared a worldwide pandemic, indicating ongoing community-level transmission of the novel influenza A (H1N1) virus in multiple areas of the world. As with the seasonal influenza, vaccination is the most effective method for preventing pandemic influenza and related complications. (CDC, MMWR 2009; 58(RR10); 1-8). However, substantial amounts of infection occurred before adequate amounts of vaccine were available. While the full impact of the H1N1 pandemic has yet to be assessed, there is a need for health care providers and suppliers to be prepared to offer any available vaccines for pandemic influenza events when vaccine becomes

available to ensure that delays in vaccine administration are minimized. Please see Section III of this preamble for a discussion of vaccine supply.

#### II. Disparities

In 1985, the Secretary of HHS issued a landmark report (colloquially known as the Heckler Report, for former HHS Secretary Margaret Heckler) which revealed large and persistent gaps in health status among different racial and ethnic groups and served as an impetus for addressing health inequalities for racial and ethnic minorities in the U.S. This report led to the establishment of the Office of Minority Health (OMH) within HHS, with a mission to address these disparities within the U.S. National concerns for these differences, termed health disparities, and the associated excess mortality and morbidity have been the focus of national health status reviews, including Healthy People 2000, 2010, and 2020.

Since the release of the Heckler Report, research has extensively documented the pervasiveness of health and health care disparities. Currently, vulnerable populations can be defined by race or ethnicity, socio-economic status, geography, gender, age, disability status, risk status related to sex and gender, and other populations identified to be at-risk for health disparities. We are aware that other populations at risk may include persons with visual, hearing, cognitive perceptual problems, language barriers, pregnant women, infants, and persons with disabilities or special health care needs.

Much attention has been given to reducing health disparities in vulnerable populations at the national level. We remain vigilant in our efforts to improve health care quality for all persons by improving health care access and by eliminating real and perceived barriers to care that may contribute to less than optimal health outcomes for all populations. We are aware that vaccination rates remain low among some minority populations. As stated above, the national influenza vaccination coverage for the 2006 through 2007 influenza season among persons age 65 and older has been estimated to be 66.8 percent; the rate is higher for non-Hispanic whites (69.3 percent) compared to non-Hispanic blacks (56.4 percent) and Hispanics (53.1 percent) (National Health Interview Survey, 2007, [http://www.cdc.gov/nchs/data/nhis/earlyrelease/200806\\_04.pdf](http://www.cdc.gov/nchs/data/nhis/earlyrelease/200806_04.pdf)). Key reasons for these disparities include differences in vaccine-seeking by patients and differences in the

likelihood of providers recommending vaccination (Herbert PL, Frick KD, Kane RL, McBean AM, "The causes of racial and ethnic differences in influenza vaccination rates among elderly Medicare beneficiaries", *Health Serv Res* 2005; 40: 517–37; Winston CA, Wortley PM, Lees KA, "Factors associated with vaccination of Medicare beneficiaries in five U.S. communities: Results from the Racial and Ethnic Adult Disparities in Immunization Initiative survey", 2003. *J Am Geriatr Soc* 2006; 54: 303–10).

We believe that expanding access to influenza vaccination through the provisions proposed in this rule would address the needs of vulnerable populations and help to diminish health and health care disparities. We believe our proposed inclusion of FQHCs among provider types covered by this proposed rule should greatly assist in this goal. For example, 71 percent of FQHC patients live in poverty and 38 percent are uninsured (<http://www.hrsa.gov/data-statistics/health-center-data/index.html>). FQHCs include several different types of health centers, including centers that focus on particularly disadvantaged groups such as migrants, homeless, public housing residents, and native Hawaiians. Therefore, we are specifically requesting comments in regard to how we could strengthen our proposed requirements to address disparities.

### III. Adequacy of Vaccine Supply

We recognize that there have been years where the release of vaccine was delayed or less than expected. For example, in the fall of 2004 there was a major shortage of inactivated influenza vaccine in the U.S. One of the major manufacturers of the influenza vaccine informed CDC in early October 2004, that none of its influenza vaccine would be available for distribution in the U.S. Because of the shortage, Federal health officials released interim guidelines as to who should receive an influenza vaccination, describing those at high-risk of influenza-related health complications as a priority group. At that time, the interim recommendations from CDC stated that people age 65 and older, as well as persons between the ages of 2 to 64 with chronic medical conditions and children ages 6 to 23 months, were to be prioritized for receiving influenza vaccination. Other groups deemed a priority were nursing home residents.

We understand that providers and suppliers may be concerned about how they would meet the requirements of this proposed rule in the event of an influenza vaccine shortage. We would not be able to require providers and

suppliers to offer vaccination if they were unable to obtain vaccine supplies. We would expect providers and suppliers to make timely efforts to acquire vaccines. In the case of limited supply, we would expect providers and suppliers to follow any guidance issued by CDC regarding priority groups for vaccination.

### IV. Provisions of the Proposed Regulations

We are proposing to require certain providers and suppliers to develop and implement policies and procedures regarding annual influenza and pandemic influenza vaccination. Pandemic procedures would be implemented when a pandemic event was announced by the Secretary. The proposed policies and procedures would be required to take into account, and reflect reasonable consideration of, guidelines established by nationally recognized organizations (for example, CDC and the American Academy of Pediatrics), including, but not limited to, guidelines addressing patients for whom vaccination may be prioritized or temporarily contraindicated.

The proposed influenza vaccination standard would (to the extent applicable) affect the following Medicare- and Medicaid-participating providers and suppliers: Hospitals (all types, including Short-term Acute Care, Psychiatric, Rehabilitation, Long Term Care, Children's, and Cancer), Critical Access Hospitals (CAHs), Rural Health Clinics (RHCs), Federally Qualified Health Centers (FQHCs), and End-Stage Renal Disease (ESRD) Facilities. We have proposed this standard for these provider and supplier types because we believe that each of them have—(a) RNs or other appropriately licensed medical personnel present when serving patients; and (b) the ability to manage vaccination and vaccine supplies with minimal additional cost or complications (for example, they already store and manage medications).

Due to the benefits that these provisions are estimated to offer (discussed later in this rule), we plan, after consideration of any comments received, to publish the proposed regulations as final in the early Fall of 2011, with the intent that they would become effective during the 2011 through 2012 influenza season. We believe that the potential consequences of not finalizing this rule as soon as possible far outweigh the burden that would be imposed on providers and suppliers. We welcome your comments on these publication and implementation plans.

Below, we set forth the influenza vaccination requirements that we propose each of the above providers and suppliers meet.

#### 1. Hospitals—Conditions of Participation: Infection Control (§ 482.42)

The following provisions of this proposed rule would apply to all hospitals in the Medicare and Medicaid programs. Section 1861(e)(1) through (e)(9) of the Act—(1) Defines the term "hospital"; (2) lists some of the statutory requirements that a hospital must meet to be eligible for Medicare participation; and (3) specifies that a hospital must also meet other requirements as the Secretary finds necessary in the interest of the health and safety of the hospital's patients. Under this authority, the Secretary has established in the regulations 42 CFR part 482, the requirements that a hospital must meet to participate in the Medicare program. Section 1905(a) of the Act provides that Medicaid payments may be applied to hospital services. Regulations at 42 CFR § 440.10(a)(3)(iii) require hospitals to meet the Medicare CoPs to qualify for participation in Medicaid.

We are proposing to add a new CoP standard for influenza vaccination at § 482.42(c). The proposed standard would require all types of hospitals regulated under the hospital CoPs to establish policies and procedures for administering annual influenza vaccinations, and pandemic influenza vaccinations in the case of a pandemic event. Pandemic procedures would be implemented when a pandemic event was announced by the Secretary. The hospital's policies and procedures would have to take into account, and reflect reasonable consideration of, the recommendations in guidelines established by nationally recognized organizations (including, but not limited to, guidelines addressing patients for whom vaccination may be prioritized or temporarily contraindicated). The proposed policies and procedures would be required to ensure that the patient was offered the influenza vaccination as soon as the vaccine was available, on or after September 1 through the end of February, except when medically contraindicated, when the patient or the patient's representative or surrogate declined vaccination, or if the patient had already received that year's vaccination.

This standard would also require hospitals to educate the patient or patient's representative or surrogate on the benefits and risks associated with the vaccination. The patient's representative or surrogate, who could

be a family member or friend that accompanied the patient, could act as a liaison between the patient and the hospital to help the patient communicate, understand, remember, and cope with the interactions that took place during the visit, and explain any instructions to the patient that were delivered by the hospital staff. If a patient was unable to fully communicate directly with hospital staff, then the hospital could give vaccination information to the patient's representative or surrogate. The patient also would have the choice of using an interpreter of his or her own or one supplied by the hospital. A professional interpreter is not considered to be a patient's representative or surrogate. Rather, it is the professional interpreter's role to pass information from the hospital to the patient. In addition, this standard would require the hospital to update the patient's health records to include (at a minimum) the date the patient or patient's representative or surrogate received education on influenza vaccination, and the date of administration or refusal of the vaccine.

Hospitals often have large outpatient populations, including those who may attend clinics (such as physical therapy clinics) that are not necessarily prepared to provide vaccine injections. This proposed rule would require that all hospital patients be offered vaccination. Therefore, we would expect that the hospital's policies and procedures address all patients, whether they were receiving inpatient or outpatient services. For example, it could be appropriate to refer certain outpatients to another clinic or department on the hospital campus if the patient wanted to receive vaccination and the outpatient was in a department of the hospital that was not equipped to administer the vaccine.

As stated above, influenza vaccination would be offered throughout the influenza season to all persons 6 months of age and older for whom vaccination is not contraindicated. Vaccination is expected to offer both direct protection to the patients receiving vaccination and indirect benefits to others by decreased exposure to infected persons.

### *2. Critical Access Hospitals—Condition of Participation: Provision of Services (§ 485.635)*

Section 1820(c)(2)(B) of the Act sets out criteria for designation as a CAH, and section 1820(e)(3) of the Act instructs the Secretary to certify a facility as a CAH if the facility, among other things, "meets such other criteria as the Secretary may require." Under

this authority, the Secretary has established CoPs for CAHs at 42 CFR part 485, subpart F. Our CoP at § 485.635 sets out our requirements regarding provision of services at CAHs.

We are proposing to add a new CoP standard for influenza vaccination at § 485.635(b). The proposed standard would require Critical Access Hospitals (CAHs) to establish policies and procedures for administering annual influenza vaccination, and pandemic influenza vaccination in the case of a pandemic event. Pandemic procedures would be implemented when a pandemic event was announced by the Secretary. The CAH's policies and procedures would have to take into account, and reflect reasonable consideration of, the recommendations in guidelines established by nationally recognized organizations (including, but not limited to, guidelines addressing patients for whom vaccination may be prioritized or temporarily contraindicated). The proposed policies and procedures would ensure that the patient was offered the influenza vaccination as soon as the vaccine was available, on or after September 1 through the end of February, except when medically contraindicated, when the patient or the patient's representative or surrogate declined vaccination, or when the patient already received that year's vaccine. This standard would also require CAHs to educate the patient or patient's representative or surrogate on the benefits and risks associated with the vaccine. The patient's representative or surrogate, who could be a family member or friend that accompanied the patient, could act as a liaison between the patient and the CAH to help the patient communicate, understand, remember, and cope with the interactions that would take place during the visit, and explain any instructions to the patient that were delivered by the CAH staff. If a patient was unable to fully communicate directly with CAH staff, then the CAH could give vaccination information to the patient's representative or surrogate. The patient also would have the choice of using an interpreter of his or her own or one supplied by the CAH. A professional interpreter is not considered to be a patient's representative or surrogate. Rather, it is the professional interpreter's role to pass information from the CAH to the patient. In addition, this standard would require the CAH to update the patient's health records to include (at a minimum) the date the patient or patient's representative or surrogate

received education on the influenza vaccination, and the date of administration or refusal of the vaccine.

As stated above, the influenza vaccine would be offered throughout the influenza season to all persons over the age of 6 months for whom vaccination was not contraindicated. Requiring CAHs to offer influenza vaccination would offer both direct protection to the patients receiving vaccination and indirect benefits to others through decreased exposure to infected persons.

### *3. Rural Health Clinics and FQHCs—Provision of Services (§ 491.9)*

We are proposing to add a new CfC standard for influenza vaccination at § 491.9(d). The proposed standard would require Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) to establish policies and procedures for administering annual influenza vaccinations and pandemic influenza vaccinations, in the case of a pandemic event. Pandemic procedures would be implemented when a pandemic event was announced by the Secretary. The clinic or center's policies and procedures would have to take into account, and reflect reasonable consideration of, the recommendations in guidelines established by nationally recognized organizations (including, but not limited to, guidelines addressing patients for whom vaccination may be prioritized or temporarily contraindicated). The proposed policies and procedures would ensure that the patient was offered the influenza vaccination, except when medically contraindicated, when the patient or the patient's representative or surrogate declined vaccination, or when the patient already received that year's vaccine.

This standard would also require RHCs and FQHCs to educate the patient or patient's representative or surrogate on the benefits and risks associated with the vaccine. The patient's representative or surrogate, who could be a family member or friend that accompanied the patient, could act as a liaison between the patient and the RHC or FQHC to help the patient communicate, understand, remember, and cope with the interactions that might take place during the visit, and explain any instructions to the patient that would be delivered by the RHC or FQHC staff. If a patient was unable to fully communicate directly with RHC or FQHC staff, then the RHC or FQHC could give vaccination information to the patient's representative or surrogate. The patient would also have the choice of using an interpreter of his or her own or one supplied by the RHC or FQHC.

A professional interpreter is not considered to be a patient's representative or surrogate. Rather, it is the professional interpreter's role to pass information from the RHC or FQHC to the patient. In addition, this standard would require the RHC or FQHC to update the patient's health records to include (at a minimum) the date the patient or patient's representative or surrogate received education on the influenza vaccination, and the date of administration or refusal of the vaccine.

As stated above, influenza vaccine would be offered throughout the influenza season to all persons over the age of 6 months for whom vaccination was not contraindicated. Requiring RHCs and FQHCs to offer influenza vaccination would offer both direct protection to the patients receiving vaccination and indirect benefits to others through decreased exposure to infected persons.

#### 4. ESRD Facility—Condition for Coverage: Infection Control (§ 494.30)

We are proposing to add a new CfC standard for influenza vaccination at § 494.30(d). The proposed standard would require ESRD facilities to establish policies and procedures for administering annual influenza vaccinations, and pandemic influenza vaccinations in the case of a pandemic event. Pandemic procedures would be implemented when a pandemic event was announced by the Secretary. The ESRD facility's policies and procedures would have to take into account, and reflect reasonable consideration of, the recommendations in guidelines established by nationally recognized organizations (including, but not limited to, guidelines addressing patients for whom vaccination might be prioritized or temporarily contraindicated). The proposed policies and procedures would ensure that each patient was offered the influenza vaccination, except when medically contraindicated, when the patient or the patient's representative or surrogate declined vaccination, or when the patient had already received that year's vaccine.

This standard would also require ESRD facilities to educate the patient or patient's representative or surrogate on the benefits and risks associated with the vaccine. The patient's representative or surrogate, who could be a family member or friend that accompanies the patient, may act as a liaison between the patient and the ESRD facility to help the patient communicate, understand, remember, and cope with the interactions that take place during the visit, and explain any instructions to the patient that are delivered by the ESRD

facility staff. If a patient is unable to fully communicate directly with the ESRD facility, then the ESRD facility may give vaccination information to the patient's representative or surrogate. The patient also has the choice of using an interpreter of his or her own or one supplied by the ESRD facility. A professional interpreter is not considered to be a patient's representative or surrogate. Rather, it is the professional interpreter's role to pass information from the ESRD facility to the patient. In addition, it would require the ESRD facility to update the patient's health records to include (at a minimum) the date the patient or patient's representative or surrogate received education on the influenza vaccination, and the date of administration or refusal of the vaccine.

As stated above, the influenza vaccine should be offered throughout the influenza season to all persons over the age of 6 months for whom vaccination is not contraindicated. Requiring ESRD facilities to offer influenza vaccination would offer both direct protection to the patients receiving vaccination and indirect benefits to others through decreased exposure to infected persons.

#### V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We believe that many of the providers and suppliers addressed in this proposed rule already offer annual influenza vaccinations, and offered the H1N1 vaccine in 2009–2010, but for the purposes of this analysis, we are assuming that all of the providers and suppliers would need to develop new policies and procedures. We are soliciting public comment on the

information collection requirements (ICRs) discussed below:

#### A. ICRs Regarding Condition of Participation: Infection Control (§ 482.42)

Proposed § 482.42(c)(1) would require a hospital to develop and implement policies and procedures regarding seasonal influenza and pandemic influenza vaccination. Proposed § 482.42(c)(2) would further specify that policies and procedures must take into account, and reflect reasonable consideration of, guidelines established by nationally recognized organizations. The hospital would also be required to comply with the conditions listed at proposed § 482.42(c)(3), which includes, but is not limited to, patient (or patient representative or surrogate) education with respect to the benefits, risks, and potential side effects of the vaccination.

The burden associated with the requirements in this section would be the time and effort necessary to develop and implement policies and procedures regarding annual influenza and pandemic influenza vaccinations. Since the policies would address annual vaccinations, there would also be an ongoing burden associated with maintaining the policies and procedures. Similarly, there would also be some burden associated with performing the patient (or patient representative or surrogate) education as stated at proposed § 482.42(c)(3). We estimate that 5,100 hospitals would be required to comply with these requirements. We also estimate that it would take 5 hours to develop, implement and annually maintain the policies and procedures for influenza vaccination. The estimated annual burden associated with developing, implementing and maintaining policies and procedures is 25,500 hours (5,100 hospitals × 5 hours per hospital). The total estimated annual cost associated with these requirements is \$1,147,500 (25,500 hours × \$45 per hour).

We further estimate that it would take each of the 5,100 hospitals 3 minutes to perform the patient or patient representative or surrogate education a total of 20,000,000 times annually. The estimated annual burden associated with this requirement is 1,000,000 hours (20,000,000 responses × .05 hours per response). The total estimated annual cost associated with these requirements is \$45,000,000 (1,000,000 hours × \$45 per hour).

*B. ICRs Regarding Condition of Participation: Provision of Services (§ 485.635)*

Proposed § 485.635 states that CAHs must develop and implement policies and procedures regarding seasonal influenza and pandemic influenza vaccination. Proposed § 485.635(b)(2) further specifies that policies and procedures must take into account, and reflect reasonable consideration of, guidelines established by nationally recognized organizations. The CAH would also be required to comply with the conditions listed at proposed § 485.635(b)(3), which include but are not limited to patient (or patient representative or surrogate) education with respect to the benefits, risks, and potential side effects of the vaccination.

The burden associated with the requirements in this section would be the time and effort necessary to develop and implement policies and procedures regarding annual influenza and pandemic influenza vaccination. Since the policies would address annual vaccinations, there would also be an ongoing burden associated with maintaining the policies and procedures. Similarly, there would also be some burden associated with performing the patient (or patient representative or surrogate) education as stated at proposed § 485.635(b)(3). We estimate that 1,300 CAHs would be required to comply with these proposed requirements. We also estimate that it would take 5 hours to develop, implement, and annually maintain the policies and procedures for influenza vaccination. The estimated annual burden associated with developing, implementing and maintaining policies and procedures is 6,500 hours (1,300 CAHs × 5 hours per CAH). The total estimated annual cost associated with these requirements is \$292,500 (6,500 hours × \$45 per hour).

We further estimate that it would take each of the 1,300 CAHs 3 minutes to perform the patient or patient representative or surrogate education. We have included the number of hours and costs for these services in the overall hospital total in the preceding discussion of burden for § 482.4.

*C. ICRs Regarding Provision of Services (§ 491.9)*

Proposed § 491.9 states that RHCs and FQHCs would have to develop and

implement policies and procedures regarding seasonal influenza and pandemic influenza vaccination. Proposed § 491.9(d)(2) further specifies that policies and procedures would have to take into account, and reflect reasonable consideration of, guidelines established by nationally recognized organizations. The RHC or FQHC would also have to comply with the conditions listed at proposed § 491.9(d)(3), which would include but not be limited to patient (or patient representative or surrogate) education with respect to the benefits, risks, and potential side effects of the vaccination.

The burden associated with the requirements in this section would be the time and effort necessary to develop and implement policies and procedures regarding seasonal influenza and pandemic influenza vaccination. Since the policies would address annual vaccination, there would also be some ongoing burden associated with maintaining the policies and procedures. Similarly, there would also be a burden associated with performing the patient (or patient representative or surrogate) education as stated at proposed § 491.9(d)(3).

We estimate that 3,800 RHCs and 1,100 FQHCs would be required to comply with these requirements. We also estimate that it would take 5 hours to develop, implement and annually maintain the policies and procedures for influenza vaccination. The estimated annual burden associated with this requirement is 24,500 hours (4,900 facilities × 5 hours per facility). The total estimated annual cost associated with these proposed requirements is \$1,102,500 (24,500 hours × \$45 per hour).

We further estimate that it would take each of the 4,900 RHCs or FQHCs 3 minutes to perform the patient or patient representative or surrogate education 25,000 times annually. The estimated annual burden associated with this requirement is 1,250,000 hours (25,000,000 responses × .05 hours per response). The total estimated annual cost associated with these proposed requirements is \$56,250,000 (1,250,000 hours × \$45 per hour).

*D. ICRs Regarding Condition: Infection Control (§ 494.30)*

Proposed § 494.30 states that ESRD facilities would have to develop and

implement policies and procedures regarding seasonal influenza and pandemic influenza vaccination. Proposed § 494.30(d)(2) further specifies that policies and procedures would have to take into account, and reflect reasonable consideration of, guidelines established by nationally recognized organizations. The ESRD facility would also be required to comply with the conditions listed at proposed § 494.30(d)(3), which would include, but not be limited to, patient (or patient representative or surrogate) education with respect to the benefits, risks, and potential side effects of the vaccination.

The burden associated with the requirements in this section would be the time and effort necessary to develop and implement policies and procedures regarding seasonal influenza and pandemic influenza vaccination. Since the policies would address annual vaccinations, there would also be an ongoing burden associated with maintaining the policies and procedures. Similarly, there would also be some burden associated with performing the patient (or patient representative or surrogate) education, as stated at proposed § 494.30(d)(3). We estimate that 5,400 ESRD facilities would be required to comply with these requirements. We also estimate that it would take 5 hours to develop, implement and annually maintain the policies and procedures for influenza vaccination. The estimated annual burden associated with this requirement is 27,000 hours (5,400 facilities × 5 hours per facility). The total estimated annual cost associated with these proposed requirements is \$1,215,000 (27,000 hours × \$45 per hour).

We further estimate that it would take each of the 5,400 ESRD facilities 3 minutes to perform the patient or patient representative or surrogate education 500,000 times annually, for a total estimated burden of 25,000 hours (500,000 responses × .05 hours per response). The estimated annual cost is \$1,125,000 (25,000 hours × \$45 per hour).

The total estimated annual cost associated with these proposed requirements is approximately \$106 million, as shown in Table 1.

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

| Regulation section(s) | OMB Control No. | Respondents | Responses  | Burden per response (hours) | Total annual burden (hours) | Hourly labor cost of reporting (\$) | Total labor cost of reporting (\$) | Total capital/maintenance costs (\$) | Total cost (\$) |
|-----------------------|-----------------|-------------|------------|-----------------------------|-----------------------------|-------------------------------------|------------------------------------|--------------------------------------|-----------------|
| \$ 482.4(c) .....     | 0938—New ..     | 5,100       | 5,100      | 5                           | 25,500                      | **45                                | 1,147,500                          | 0                                    | 1,147,500       |
|                       |                 | 5,100       | 20,000,000 | .05                         | 1,000,000                   | **45                                | 45,000,000                         | 0                                    | 45,000,000      |
| \$ 485.635(b)         | 0938—New ..     | 1,300       | 1,300      | 5                           | 6,500                       | **45                                | 292,500                            | 0                                    | 292,500         |
| \$ 491.1 .....        | 0938—New ..     | 4,900       | 4,900      | 5                           | 24,500                      | **45                                | 1,102,500                          | 0                                    | 1,102,500       |
|                       |                 | 4,900       | 25,000,000 | .05                         | 1,250,000                   | **45                                | 56,250,000                         | 0                                    | 56,250,000      |
| \$ 494.30 .....       | 0938—New ..     | 5,400       | 5,400      | 5                           | 27,000                      | **45                                | 1,215,000                          | 0                                    | 1,215,000       |
|                       |                 | 5,400       | 500,000    | .05                         | 25,000                      | 45                                  | 1,125,000                          | 0                                    | 1,125,000       |
| Total .....           | .....           | 16,700      | 45,516,700 | .....                       | 2,358,500                   | .....                               | .....                              | .....                                | 106,132,500     |

\* \$31.31 is the mean hourly wage of a registered nurse according to the Bureau of Labor Statistics of the U.S. Department of Labor (<http://www.bls.gov/oes/current/oes291111.htm#nat>). We have increased this rate to include the fringe benefits and overhead costs of these staff, for a total of \$45 an hour, rounded. Fringe benefits equal about 30% of total compensation, according to the BLS (<http://www.bls.gov/news.release/ecec.nr0.htm>). We assume that nurses will be the professional staff primarily involved in establishing policies and procedures, performing patient education, and administering vaccines, and that other staff involved will have hourly wages both higher and lower than nurses, but on average a similar amount.

\*\* Totals for these functions may differ slightly from those in RIA analysis due to rounding. Note that the RIA contains several categories of costs, such as vaccines and vaccine administration, that are not PRA costs.

If you comment on these information collection and recordkeeping requirements, submit your comments electronically as specified in the ADDRESSES section of this proposed rule.

**VI. Regulatory Impact Analysis**

*A. Introduction*

We have examined the impacts of this rulemaking as required by Executive Orders 12866 (September 1993) and 13563 (January 2011). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects (\$100 million or more

in any 1 year). This proposed rule has been designated an “economically significant” regulatory action under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

*B. Statement of Need*

We have determined that these proposed CoPs and CfCs would protect public health and safety and ensure high quality care to patients in the settings that would be subject to this requirement. Increasing the utilization of effective preventive services is a goal of both CMS and CDC. We believe that this proposed rule would facilitate the delivery of appropriate vaccinations in a timely manner, increase vaccination coverage levels, and decrease morbidity and mortality rates associated with seasonal influenza. We believe that the “required request” approach we are proposing would encourage patients to receive desired vaccinations without expending both time and trouble to find out where to obtain them, and allow them to obtain expert and

individualized advice. Patients could receive vaccinations without making an extra trip to a medical care provider or inconveniently waiting to receive service. As a result, we expect the costs of the proposal would be far lower per patient served than alternatives, the resulting rates of vaccination and protection from influenza far higher, the economic and life-saving benefits substantial, and the net effects overwhelmingly beneficial.

*C. Overall Impact*

We estimate in the analysis that follows that the costs associated with this proposed rule would be approximately \$330 million annually and that its quantifiable, monetized benefits would be approximately \$830 million annually, reflecting decreased medical care costs (\$710 million) and savings in patient time (\$120 million). In addition, the proposed rule would have substantial life-saving effects that we have not quantified. The distribution of medical costs and savings by payer is summarized in the table below:

TABLE 2—DISTRIBUTION OF MEDICAL COSTS AND SAVINGS  
[\$ In millions]

| Primary payer           | Gross vaccination cost | Reduced treatment costs to payers | Net cost to payers |
|-------------------------|------------------------|-----------------------------------|--------------------|
| Medicare .....          | \$165                  | –\$545                            | –\$380             |
| Medicaid .....          | 35                     | –35                               | 0                  |
| Private Insurance ..... | 130                    | –130                              | 0                  |
| Total .....             | 330                    | –710                              | –380               |

As described in more detail below, we estimate that all categories of payers would at least break even in financial terms. There is substantial uncertainty

over both the cost and benefit estimates, and we believe that either estimate could be as much as 50 percent higher or lower.

*D. Anticipated Costs*

In order to comply with this rule, providers and suppliers would need to develop the necessary policies and

procedures to be followed by staff as standard practices. In Table 3, we estimate that the number and types of

providers potentially subject to the proposed rule would be as follows:

TABLE 3—ESTIMATED NUMBER OF PROVIDERS & SUPPLIERS AFFECTED BY THE INFLUENZA VACCINATION PROPOSED RULE\*

| Provider/supplier   | Number        |
|---|---------------|
| Hospitals (incl. Psychiatric and Inpatient Rehabilitation Facilities) ..... | 5,100         |
| Critical Access Hospitals (CAHs) .....                                      | 1,300         |
| Rural Health Clinics (RHCs) .....   | 3,800         |
| Federally Qualified Health Centers (FQHCs) .....                            | 1,100         |
| End-Stage Renal Disease Facilities (ESRD Facilities) .....                  | 5,400         |
| <b>Total Providers and Suppliers .....</b>                                  | <b>16,700</b> |

In Table 4, we present our estimate of the likely annual time and costs that providers and suppliers would need to spend each year in policy development

and planning activities. Because each influenza season is unique, and because there are periodic updates to vaccine recommendations and advice, as well as

local variations in disease incidence each year, we estimate that these costs would continue to be incurred each year.

TABLE 4—ESTIMATED ANNUAL POLICY AND PROCEDURE IMPLEMENTATION COSTS RELATED TO THE INFLUENZA VACCINATION PROPOSED RULE

|   |               |
|---|---------------|
| Number of Providers/Suppliers .....                           | 16,700        |
| Hours spent per Provider/Supplier .....                       | 5             |
| Total hours .....   | 83,500        |
| Cost per hour** .....   | \$45          |
| <b>Total cost to providers and suppliers (millions) .....</b> | <b>\$3.75</b> |

\* Source is CMS data on participating Medicare providers.  
 \*\* See Table 1 for basis of hourly cost estimate.

This rule proposes that the patient's vaccination status be documented in the patient's medical record. The status must indicate, at a minimum, the following: that the patient (or the patient's representative or surrogate) was asked whether the patient was already vaccinated; that patients not already vaccinated were provided education regarding the benefits, risks,

and potential side effects of influenza vaccination; and that these patients either received the influenza vaccination or did not receive the influenza vaccination due to medical contraindications, previous influenza vaccination during the current influenza season, or patient refusal. We estimate that documentation would take approximately 0.6 minutes per patient,

one percent of an hour, taking into account all situations (for example, whether the patient had already received the vaccine, or newly received the vaccine).  
 Tables 5 and 6 summarize the likely effects of this proposed requirement, based on patient volume at each type of facility.

TABLE 5—ESTIMATED NUMBER OF PATIENTS BY TYPE OF PROVIDER & SUPPLIER

| Provider/supplier   | Number             |
|---|--------------------|
| Hospitals (incl. Psychiatric and Inpatient Rehabilitation Facilities) * ..... | 20,000,000.        |
| Critical Access Hospitals (CAHs) * .....                                      | Incl. above.       |
| Rural Health Clinics (RHCs) .....   | 5,000,000.         |
| Federally Qualified Health Centers (FQHCs) .....                              | 20,000,000.        |
| End-Stage Renal Disease Facilities (ESRD Facilities) .....                    | 500,000.           |
| <b>Total Patients .....</b>   | <b>45,500,000.</b> |

\* Hospital and CAH data assume one half of annual discharges; all others use annual caseload of unique patients.

TABLE 6—ESTIMATED ANNUAL MEDICAL RECORD COSTS RELATED TO THE INFLUENZA VACCINATION PROPOSED RULE

|   |                |
|---|----------------|
| Number of patients (millions) .....                           | 45.5           |
| Hours spent per patient .....                                 | .01            |
| Total hours (millions) .....                                  | .45            |
| Cost per hour* .....  | \$45           |
| <b>Total cost to providers and suppliers (millions) .....</b> | <b>\$20.2M</b> |

\* See Table 1 for basis of hourly cost estimate.

In addition, facility staff would need to ask the questions above (that is, ascertain vaccination status, and explain the risks and benefits to patients who have not previously been vaccinated). We estimate that this process would take an average of 3 minutes, or 0.05 of an hour, as shown in Table 7.

TABLE 7—ESTIMATED ANNUAL PATIENT INQUIRY AND COUNSELING COSTS RELATED TO THE INFLUENZA VACCINATION PROPOSED RULE\*

|  |        |
|--|--------|
| Number of patients (millions) .....                    | 45.5   |
| Hours spent per patient .....                          | .05    |
| Total hours (millions) .....                           | 2.3    |
| Cost per hour** .....                                  | \$45   |
| <hr/>  |        |
| Total cost to providers and suppliers (millions) ..... | \$103M |

\* Most data from preceding tables.

\*\* See Table 1 for basis of hourly wage estimate.

For those patients who agree to receive vaccination, time would be required to obtain and position supplies and equipment, to perform the vaccination, and to dispose of sharps. We estimate that, on average, this would take an additional 6 minutes per patient, or 0.1 of an hour. For purposes of this analysis, we assume that twenty percent of all patients have been vaccinated before the provider request is made. The basis for this estimate is that since overall about 40 percent of Americans currently are vaccinated over the course of the influenza season ([http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5908a1.htm?s\\_cid=rr5908a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5908a1.htm?s_cid=rr5908a1_e)), about half of these persons would have been vaccinated before one of the provider encounters covered by this proposed rule. We estimate that one half of the remainder (40 percent) would agree to be vaccinated, for a total vaccination rate among these persons of 60 percent (see sensitivity discussion later in this analysis). We also estimate that the elderly would be disproportionately likely to take the vaccine, since the risks they face, which would have been explained to them, are so much higher

than the general patient population. We have found no empirical basis for any estimate in the literature, but believe that a specific request to patients already being served by the facilities covered by this proposed rule is likely to substantially increase the proportion of the population agreeing to what, under this rule, would be a far more convenient health care offering. We welcome comments on this assumption.

Finally, we also assume that one half of the additional 40 percent would have been vaccinated elsewhere, later in the influenza season, so that only half of this amount represents additional vaccination costs to society. In other words, absent these proposed requirements, 40 percent of these persons would have been vaccinated somewhere else, but these encounters lead half of that 40 percent to be vaccinated by the providers affected by this proposed rule rather than elsewhere.

Accordingly, assuming that the patient population at these facilities on average reasonably approximates the vaccination status of the population at large, the total percentage of these patients we estimate will ultimately be

vaccinated will rise to 60 percent from 40 percent (20 percent already vaccinated plus 40 percent newly vaccinated equals 60 percent total vaccination rate), but the net increase in those vaccinated is only half of the number vaccinated at these facilities (20 percent already vaccinated plus 40 percent newly vaccinated less the 20 percent who would later have been vaccinated equals the same 60 percent total vaccination rate). Using these same fractions, the net cost of vaccine administration for these patients is not the amount we estimate in the “total cost” line of Table 7 will be spent at these facilities, but that amount less spending on the 20 percent who would later have been vaccinated elsewhere, for a “net cost to society” line in Table 8 that is only half as large. We emphasize that these are rough estimates intended to show the general magnitudes of the effects of the proposed rule. Therefore, although we estimate these providers would vaccinate half of those not already vaccinated, the total percentage of the patient population in these settings we estimate will be vaccinated is 60 percent, not 80 percent.

TABLE 8—ESTIMATED ANNUAL VACCINATION ADMINISTRATION COSTS RELATED TO THE INFLUENZA VACCINATION PROPOSED RULE

|   |          |
|---|----------|
| Number of patients vaccinated under this rule (millions)* ..... | 18.2     |
| Hours spent per patient .....                                   | .1       |
| Total hours (millions) .....                                    | 1.8      |
| Cost per hour** .....   | \$45     |
| Total cost to providers and suppliers (millions) .....          | \$81M    |
| Less reduction in costs to other providers (millions) .....     | –\$40.5M |
| Net cost to society (millions) .....                            | \$40.5M  |

\* Forty percent of total patients.

\*\* See Table 1 for basis of hourly cost estimate.

In addition, these patients would receive the vaccine itself. The cost of the vaccine is not well established in the literature, in part because the existence of substantial government intervention in the market, and special prices for

public purchasers, complicate the matter. Medicare itself pays about \$12 per dose, and for purposes of this analysis we assume that about half of the patients who would otherwise not be vaccinated are Medicare or Medicaid

beneficiaries, that the price to Medicare or Medicaid is therefore applicable to half of all patients who would be vaccinated under this proposed rule. In this regard, about 40 percent of all hospital admissions are for the elderly

and almost half of all FQHC patients are Medicare (7 percent) or Medicaid (37 percent) participating (See 2009 Data Snapshot for health center data at <http://www.hrsa.gov/data-statistics/health-center-data/NationalData/2009/2009datasnapshot.html>). Medicare and Medicaid between them finance the

great majority of care for the elderly, who are most at risk to influenza infection and related complications, most likely to be served by providers subject to the proposed rule, and, therefore we estimate, most likely to agree to be vaccinated. We further assume that the price for private-pay

patients is twice as high, for an average of \$18 across all publicly and privately financed patients. Based on these assumptions, and previous tables, Table 9 shows the cost of vaccine under the proposed rule.

TABLE 9—ESTIMATED ANNUAL VACCINE COSTS RELATED TO THE INFLUENZA VACCINATION PROPOSED RULE

|  |           |
|--|-----------|
| Number of patients vaccinated under this rule (millions)* .....                        | 18.2M     |
| Average vaccine cost per patient .....   | \$18      |
| Total cost billed through these providers and suppliers (millions) .....               | \$327M    |
| Less reduction in cost billed through other providers and suppliers** (millions) ..... | -\$163.5M |
| Net cost to society (millions) .....   | \$163.5M  |

\* Forty percent of total patients.

\*\* Twenty percent would have been vaccinated by other providers.

Unlike the previous tables, which estimated initial costs to providers and supplier subject to this proposed rule, we assume that none of the costs of vaccine will be paid by those entities. Instead, in the vast majority of cases the cost of the vaccine will be paid by public or private insurers, and in most of the remainder by the patients themselves. In total, we estimate (tables 4, 6, 7, and 8) that providers and suppliers covered by this proposed rule would incur total annual costs of about \$170 million (\$3.75M, \$20.2M, \$103M, and \$40.5M respectively). Almost all of this would be reimbursed by insurance or charges to patients, so the net cost to providers would be far less. The total cost per provider and supplier, however, would average only about \$5,000 even if they bore all of the cost. Since hospitals and FQHCs each account for almost half of all patients affected by this proposed rule, they would incur the great majority of these costs. Other provider and supplier types would incur far lower costs, because they have far fewer patients on average.

Another way to look at these costs is on a per-patient basis. Taking into account all costs including vaccines, whether incurred by providers, patients, or third-party insurance (including Medicare and Medicaid), the costs of the proposed rule are about \$330 million annually for those who would not otherwise have been vaccinated. Based on the estimates above, the gross total cost of vaccination is about \$30 per person, and the net cost \$18 per person. This latter figure actually overestimates the net cost, since it assumes that the cost in other settings is identical, which it is not (see the discussion which follows). Vaccination incidental to a medical encounter for another purpose (for example, dialysis or surgical procedure) saves substantial costs in

patient and provider time compared to a standalone visit.

We have not incorporated one major cost reduction in the preceding tables. Because we estimate that half of the 18 million patients vaccinated under this rule would have been vaccinated in other settings at a later time, those patients would avoid the sometimes substantial costs of time and inconvenience they would otherwise have incurred. On average, a separate trip to a medical care provider to be vaccinated is likely to consume close to an hour. For example, a trip to a drug store might involve a 20 minute drive, a 20 minute wait in line, and a 20 minute drive home. A trip to a physician office might take even longer. Assuming that patient time is valued at \$20 an hour, and that the 9 million patients estimated as likely to have been vaccinated elsewhere had they not been vaccinated in one of the settings proposed in this rule, the potential time savings are on the order of 9 million hours, valued potentially at \$180 million. (Note: \$20 an hour is a very rough estimate taking into account that in most cases patients use leisure time rather than otherwise paid time for non-emergency visits; this value has been used in other Federal analyses of consumer time.) Some of these patients would have found ways to combine these visits with other trips to the same settings, but even if one third of them had done so, time savings would still be perhaps 6 million hours and \$120 million. (There are also provider savings, but these are estimated in the preceding tables.) The time savings to these patients are a substantial additional benefit of this rule, reducing time spent by most from roughly one hour plus a few minutes for actual vaccine administration to just the few minutes for vaccine administration.

It is possible that an increase in the number of influenza vaccinations provided may result in a slight increase in the number of adverse events. Persons who experience an adverse event as a result of an influenza vaccination may be eligible for compensation under the National Vaccine Injury Compensation Program.

*E. Anticipated Benefits*

For purposes of a point estimate of benefits, we estimate above that the overall vaccination rate, by the end of the influenza season, would rise from about 40 percent to about 60 percent as the net result of this rule, if issued in final as proposed, for approximately 45 million covered patients. That corresponds to a net additional 9 million persons vaccinated. These persons would on average be younger than those protected under the rule issued in 2005 to protect the disproportionately elderly patients in long term care facilities, but would on average be far older than the population at large simply by virtue of Medicare or Medicaid coverage and disproportionate use by the elderly of providers addressed under this proposed rule. This estimate of effectiveness is heavily influenced by the results of the recent initiative to increase vaccination rates among nursing home residents. It appears that person-to-person counseling by health care professionals, especially to elderly patients already under care, with vaccination conveniently available after patient assent, is vastly more effective in obtaining patient participation than generalized public awareness campaigns or simple availability of insurance coverage. For example, a person willing to be vaccinated after a public awareness campaign would still have to identify a participating provider, travel to the vaccination location, arrive at a

time when the service is offered, and wait for service (in many settings patients wait in long lines). The patients addressed by this proposed rule avoid such inconvenience and cost.

The benefits of influenza vaccination in preventing morbidity and mortality are highest among the elderly, so the benefits of this proposed rule would not be as high, per person, as under the 2005 rule, which addressed the overwhelmingly elderly population of nursing homes. We nonetheless estimate the benefits of this proposed rule as very substantial, many times higher than the cost of the rule. Rates of influenza infection, seriousness of illness, vaccine effectiveness, and mortality prevention all vary by age of patient and by health status of patient. For example, a recent study estimates the average annual rate of influenza-associated deaths with underlying respiratory and circulatory causes to be .2 per 100,000 persons in the population from infancy through age 18, 1.5 per 100,000 persons from age 19 through age 64, and 66.1 per 100,000 persons at age 65 or above (M.G. Thompson, *et al.*, "Estimates of Deaths Associated with Seasonal Influenza—United States, 1976–2007," CDC, MMWR 10, 59(33): 1057–1062).

We do not have detailed data on age and medical conditions for all of the settings to which this proposed rule would apply. However, a substantial majority of hospital patients are middle-aged (20 percent ages 45 to 64) or elderly (40 percent ages 65 or older), and hospital patients account for almost half of those that this proposed rule would affect.

Based on its own conclusions from recent research, ACIP recommends seasonal influenza vaccination at all ages (for a highly detailed discussion, see "Prevention and Control of Seasonal Influenza with Vaccines," *op cit*, pages 27–28): "Influenza vaccine should be provided to all persons who want to reduce the risk for becoming ill with influenza or of transmitting it to others. However, emphasis on providing routine vaccination annually to certain groups at higher risk for influenza infection or complications is advised, including all children aged 6 months–18 years, all persons aged greater than 50 years, and other adults at risk for medical complications from influenza."

Recent literature suggests the benefits of vaccination for influenza would outweigh costs for populations of all ages, regardless of overall risk categories (of course, vaccination would be contraindicated for some specific patients; these are broad population estimates).

Another recent study put the potential economic and life saving benefits of vaccination in clear perspective (Molinari, Noelle-Angelique, *et al.*, "The Annual Impact of Seasonal Influenza in the U.S.: Measuring Disease Burden and Costs," Vaccine 25 (2007), pages 5086–5096). This study calculated the total annual economic burden of influenza, including medical costs, lost earnings, and lost life, at about \$87 billion annually (in 2003 dollars).

The effectiveness of vaccination in preventing morbidity and mortality presents another major uncertainty. Among children, for example, it depends on which type of vaccine is used, and whether one or two doses are given, in addition to risk status, virulence of the virus in a particular year, and how well the vaccine for a particular year matches the virus strains circulating that year. Study results also vary widely because it is difficult to control for underlying risk factors. As previously discussed in this preamble, the patients of both hospitals and health centers are disproportionately likely to fall in the least healthy categories. The ACIP report, "Prevention and Control of Seasonal Influenza with Vaccines," compares the results of vaccine effectiveness studies and finds typical results to fall between 27 and 70 percent effectiveness in preventing hospitalization for pneumonia and influenza among elderly adults.

The 2005 final rule (70 FR 58834), discussed earlier in this preamble, estimated that in long term care facilities a 16 percent increase in the percent vaccinated annually would increase the number vaccinated by 320,000, reduce the number of illnesses by 10,000, reduce the number of hospitalizations by 5,300, and reduce the number of deaths by about 2,300.

The projected increase in vaccination under this proposed rule for persons aged 65 or older would be approximately 3.2 million persons if we assume that 40 percent of 20 million persons are aged 65 or older and that this population would have an additional take up rate of 40 percent. If we assume that immunization for the hospitalized elderly is roughly half as effective in preventing illness compared to immunization for the long term care population (that is, prevents illness in 1.5% of the immunized rather than 3%), the additional vaccination would result in a reduction in number of illnesses in this group of about 50,000. If we assume that the likelihood of hospitalization is somewhat higher in the non-institutionalized group (those institutionalized already receiving 24-hour medical care), the reduction in

illnesses might reduce the number of hospitalizations by about 35,000.

In contrast to the long term care situation, however, the same patients are unlikely to present to providers and suppliers affected by this proposed rule year after year (the major exception to this point would be ESRD patients). Finally, it is unlikely that the risks of hospitalization and death are as high in the elderly population at large, or even the elderly population already hospitalized or being served in other provider settings, as in long term care facilities. Unfortunately, none of the existing literature estimates lives saved for persons who are already in medical care settings, in many cases very ill, as contrasted to persons of the same age who are not acutely ill or in some cases (for example, ESRD patients) chronically ill.

All of these uncertainties are so substantial that we cannot estimate with any confidence the numbers of lives likely to be saved. Likewise, estimates of the value of lives saved would not only reflect these uncertainties, but also the many uncertainties surrounding such valuations. Accordingly, we do not attempt to estimate in either quantitative or dollar terms the very substantial life-saving benefits of this proposed rule.

There are also uncertainties surrounding the likely reductions in morbidity and medical treatment costs for these patients, but those are far less. Accordingly, we have used adjusted estimates from the 2005 rule of \$10,000 per hospitalization to provide a rough estimate of future medical care savings. By far the largest category of savings, in dollar terms, results from hospitalizations prevented. In total, we estimate medical care savings to be approximately \$710 million annually, as detailed in the analysis that follows.

#### F. Distribution of Costs and Benefits

The estimates presented in this analysis are primarily based on economic costs and benefits to providers and patients. Such estimates do not address who pays. In this section of the analysis we analyze the likely incidence of costs and savings to various categories of payers, including insurance programs and patients themselves.

Absent detailed data on the rapidity and extent of future adjustments, or of the rapidity and extent of future adjustments in insurance payments (for example, to what extent will Medicare or other insurance payments to hospitals reflect vaccine administration costs), it is impossible to make precise estimates of the incidence of costs.

However, it is likely that about two-fifths of the affected patients would be elderly Medicare beneficiaries. Because Medicare pays less for vaccine than other payers, Medicare would therefore pay roughly one-fourth of the cost of vaccine and vaccine administration costs, or about \$80 million annually, for elderly Medicare patients (some of this cost would be borne by the elderly, through their share of the Part B premium). Assuming that all of the hospitalizations prevented among the elderly would be Medicare patients, that the average cost of an influenza hospitalization is on the order of \$10,000 for Part A costs, and that 35,000 elderly hospitalizations would be avoided, offsetting savings to the Medicare program from reduced hospitalization would be about \$350 million, less roughly \$10 million for the Part A deductible, for a net Part A saving to the government of \$340 million. There would also be ambulatory cost savings. For hospitalized patients we assume these would average \$2,000, for gross savings of \$50 million and net savings to the government of \$40 million after cost sharing. Assuming 50,000 fewer illnesses in this group not leading to hospitalization, and an average of one visit per patient at an average cost of \$350, ambulatory savings to Medicare for these elderly patients would be about \$15 million after patient cost sharing. These calculations lead to an estimate of savings to the government of \$350 million for Part A patients age 65 and older, and of \$65 million for Part B patients 65 and older. The total would be \$430 million under these assumptions and calculations. These estimates assume that the numbers of hospitalizations and illnesses prevented among the elderly would be at slightly

over half the rate estimated for the long term care vaccination program, and are correspondingly sensitive to changes in this assumption.

The estimates above are for elderly participants in Medicare. However, about one-fifth of beneficiaries enrolled in Medicare are disabled rather than elderly. Assuming that disabled beneficiaries are roughly as likely as the elderly to use the providers that would be affected by this proposed rule, to accept the offer, and to benefit (they are younger, but less healthy, on average), we would expect the savings and cost estimates to be roughly 20 percent higher than the figures above for the Medicare program as a whole. The total net savings to the Medicare program would be approximately \$540 million in the first year, based on the assumptions above.

We note that patients would not bear directly any of the vaccine or vaccine administration costs. Insured patients would gain from reductions in both inpatient and outpatient incidence of influenza-caused treatment through reduced coinsurance and copayments for the treatments they would otherwise receive. The uninsured would gain from elimination of inpatient and outpatient charges to which they would otherwise be exposed.

Other insurers, including Medicaid, would incur costs roughly in proportion to their share of the population in the settings we propose to cover, and taking into account whether they are primary or secondary. Absent precise data, we think it likely that Medicaid would be affected roughly in proportion to its coverage of the non-elderly and non-disabled population (for whom Medicare is primary), realizing vaccine and vaccine administration costs of roughly 10 percent of the total.

Accordingly, Medicaid payments to providers would be on the order of \$30 million a year (ten percent of \$330 million in costs incurred by providers). These payments would be financed through the same Federal and State shares as other Medicaid payments for these services. Medicaid savings would be far lower, proportionally, than Medicare costs because the incidence of hospitalization among younger influenza patients is so much lower. We think it reasonable to assume that hospitalization savings would roughly equal and quite possibly exceed vaccine administration costs, so that the net effect of the rule on Medicaid costs would be close to zero, or even cost-saving. We emphasize that these are very rough estimates.

We have no better basis for estimating costs or savings to private insurers. Overall, we think that they will pay about half of the costs of the program. Because their enrollees are generally below age 65, and if above such age have Medicare as primary insurance, their savings from reduced medical care costs will reflect the far lower incidence of influenza morbidity and mortality at younger ages, and the correspondingly lower potential cost savings. Similar to our conclusion for Medicaid, we think it reasonable to assume that savings to private health plans would likely approximate the costs of the program, and would in any event have a negligible effect on overall costs. Again, we emphasize that these are very rough estimates.

Accordingly, as outlined in Table 10, all categories of payers would at least break even in financial terms, and those that disproportionately serve the oldest and sickest, notably Medicare, would likely achieve substantial savings in relation to their costs.

TABLE 10—DISTRIBUTION OF MEDICAL COSTS AND SAVINGS

[\$ In millions]

| Primary payer           | Gross vaccination cost | Reduced treatment costs to payers | Net cost to payers |
|-------------------------|------------------------|-----------------------------------|--------------------|
| Medicare .....          | \$165                  | –\$545                            | –\$380             |
| Medicaid .....          | 35                     | – 35                              | 0                  |
| Private Insurance ..... | 130                    | – 130                             | 0                  |
| Total .....             | 330                    | – 710                             | – 380              |

*G. Uncertainty of the Estimated Costs and Benefits*

Clearly, both these cost and benefit estimates are subject to substantial uncertainty. For example, actual rates for vaccination may be considerably

higher or lower than those we have estimated. Some covered providers and suppliers are already taking the steps, incurring the costs, and helping their clients attain the life-saving benefits we have estimated. However, the preponderance of the evidence

discussed earlier in this preamble suggests that the present level of effort is low. Due to this and other uncertainties, we believe that the costs and benefits actually realized under the proposed rule could easily be half, or double, our estimates. Perhaps the

greatest uncertainty lies in our estimate that roughly half of the patients who would otherwise be unvaccinated will accept the vaccination offers made under the proposed rule. If the incremental proportion were to be only one-fourth, both costs and benefits would be halved. If almost all patients accepted the offers, both costs and benefits would be approximately doubled. We think both extremes are quite unlikely (for example, some patients will be firm refusers of vaccine no matter how well the offer is made). We do not, however, have great confidence that the incremental percentage will be at or near 50 percent, rather than 40 percent or 60 percent. Another area of uncertainty is the effectiveness of the vaccine in preventing influenza, particularly among the elderly, with estimates quoted previously in this analysis ranging from 27 to 70 percent. There will be some independent effect from the recently issued rule on coverage of preventive health services by health insurance plans, but that rule contained no estimate of resulting vaccination improvements and we have no way to take those into account in our estimates. As another example of the caution that should be used in interpreting these estimates, dollar estimates of benefits depend crucially not only on these take-up rates, but also on the uncertain extent to which these types of atypical patients would otherwise have been hospitalized had they become ill from influenza.

As previously discussed, we do not include an estimate in either quantitative or dollar terms of the very substantial life-saving benefits of this proposed rule in our primary estimate. However, if as many as 5,000, 10,000, or even 20,000 deaths from influenza complications could be avoided, even a very conservative value per life saved could yield many billions of dollars in benefits.

Throughout this analysis, we have used rounded numbers to emphasize that none of the assumptions, calculations, and estimates should be taken as precise or certain. We welcome comments on all assumptions and calculations.

#### *H. Effects of Pandemic Provisions*

We have not attempted to quantify the costs or benefits of the proposed requirements regarding preparation for, and services under, potential future pandemics. We believe that the costs of planning and developing procedures for such services fall within the estimates we have developed for annual influenza. The actual costs of

vaccination, and benefits thereof, are essentially unpredictable. No one knows when another pandemic may arrive. We believe, however, that the potential benefits exceed the potential costs to at least the same degree as for annual influenza. We welcome comments and information on this conclusion, and any quantitative information that may shed more light on costs and benefits.

#### *I. Alternatives Considered*

We considered other alternatives regarding vaccinating patients and residents against influenza.

One alternative would be to keep the present rules, as they are written (that is, no requirements). The current regulations, however, have so far not been effective in increasing the annual rate of influenza vaccination, with the notable and extremely important exception of long term care facility patients. The increase in percent vaccinated in this high-risk group to approximately 90 percent (as discussed previously) demonstrates unequivocally the potency of the "routine request" protocol recently applied to that group and herein proposed for additional tens of millions of patients.

Outside long term care settings, despite the Federal government's unified efforts to increase the availability of safe and effective vaccines, and despite substantial progress in reducing many vaccine preventable diseases, many at-risk individuals and care-givers are not receiving influenza vaccines. Section 4107 of the Balanced Budget Act of 1997 extended the influenza vaccination campaign being conducted by CMS in conjunction with CDC and the National Coalition for Adult Immunization through fiscal year 2002, authorizing \$8 million for each fiscal year from 1998 to 2002. Although Medicare reimbursement for influenza vaccination was increased under this legislation, rates of vaccination did not improve as anticipated. This suggests that neither improved payment nor traditional campaigns are likely to lead to substantial improvements in annual vaccination rates.

Another alternative would be to explore untried ways to educate providers on the value of influenza vaccines without rulemaking. However, as discussed in studies cited earlier in this rule, provider education, so far, has not been effective in improving vaccination rates.

There are a number of additional alternatives that we have considered within the context of the proposed rule.

We have not proposed requiring these providers and suppliers to offer

pneumococcal vaccine, in contrast to the 2005 rule for long term care facilities. Pneumococcal vaccine is recommended for all children less than 59 months old. In addition, children older than 24 months who are at high risk of pneumococcal disease, adults over the age of 65, and adults under age 65 with certain risk factors are recommended to receive the pneumococcal vaccine. While there is a large population that could benefit from pneumococcal vaccination, the vaccine should only be given once or twice, depending on the patient's age. Because it is not designed or recommended for regular administration, we believe it is best provided or prescribed by primary care physicians who maintain long-term records for patients. We welcome comments on this tentative decision, and information on any research evidence that might bear on the issue.

The precise timing of vaccination and the precise populations to be offered vaccination may vary from year to year, depending on the availability of vaccine. We considered various ways of providing flexibility for supply problems, and concluded that the best way to handle such contingencies without having to engage in rulemaking annually, or in situations where conditions change too rapidly for normal rulemaking procedures, would be to require that facility planning take into account the latest recommendations of appropriate expert bodies.

We considered both expanding and contracting the categories of suppliers and providers covered in this rule. The set we have chosen have in common two key factors: (1) in each setting the patients present before health care providers with staff licensed to provide vaccination available at the time and location of the encounter, and (2) ready access to equipment and storage appropriate for handling, controlling, and administering vaccine. In contrast, home health agency aides (as an example) are rarely, if ever, registered nurses, and would not normally have the means to transport refrigerated vaccines. Hospices, while capable of administering vaccine, would be inappropriate providers for this purpose because of the terminal health situations faced by their patients.

We also considered requiring providers to offer vaccination only to higher risk patients, such as those over 45 years of age or over 65 years of age. A variation would be for providers to use medical risk categories, such as suppressed immune system or weak heart or lung function, to identify patients most in need of vaccine protection at all ages. We do not

propose such alternatives, but welcome comment on them. The reasons for not departing from a universal requirement are threefold. First, all patient categories, even healthy children, have now been shown to benefit from vaccination. All payers and providers roughly break even (or do better) from a universal, uniform practice. Second, such alternatives add complexity and cost if based on diagnostic or other medical indicators requiring individualized decisions about each patient, and are arguably too simplistic or arbitrary otherwise. For example, a 64-year-old may not be any less likely to benefit from vaccination than a 65-year-old. Third, and of great practical importance, if a provider has any substantial number of patients in any mandatory group (for example, patients over age 65), the provider will have to do the same planning, develop the same

protocols, provide the same staff training, go through the same vaccine ordering and storage procedures, *etc.* as it would if all patients were covered. While a precise calculation is difficult, it appears that there are significant economies of scale and very little savings in burden to providers from covering all patients.

We welcome comments on these and any other alternatives that would improve the rule.

*J. Accounting Statement*

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>), in Table 10, we have prepared an accounting statement showing the classification of the costs and benefits associated with the provisions of this proposed rule. The accounting statement is based on

estimates provided in the RIA. Because we assume that costs and benefits remain constant in real terms over the years, the discounted costs and benefits, when “annualized” to an average yearly amount, are the same as the one year/first year estimates provided throughout this analysis. We have used as an estimating horizon a 10-year period, which is the lowest normally used in Regulatory Impact Analyses. We would not expect, however, that the estimates would in fact remain as projected. As emphasized repeatedly throughout this analysis, our estimates are very rough and we would not be surprised to see real world effects that are substantially higher or lower. For purposes of this table, we have used a low estimate that is half our primary estimate, and a high estimate that is double our primary estimate.

TABLE 11—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS AND SAVINGS

[\$ In millions]

| Category   | Primary estimate                                  | Low estimate                                      | High estimate                                     | Units        |                         |                 |
|--|---|---|---|--------------|-------------------------|-----------------|
|  |   |   |   | Year dollars | Discount rate (percent) | Period covered* |
| <b>Benefits</b>  |   |   |   |              |                         |                 |
| Annualized Qualitative (Unquantified) Value of Lives Saved among Patients Immunized. | Thousands of lives saved but no precise estimate. | Thousands of lives saved but no precise estimate. | Thousands of lives saved but no precise estimate. | 2011         | 7                       | 2011–20         |
|  | Thousands of lives saved but no precise estimate. | Thousands of lives saved but no precise estimate. | Thousands of lives saved but no precise estimate. | 2011         | 3                       | 2011–20         |
| Annualized Value of Travel and Convenience Savings to Patients Immunized.            | \$120 .....                                       | \$60 .....  | \$240 .....                                       | 2011         | 7                       | 2011–20         |
|  | \$120 .....                                       | \$60 .....  | \$240 .....                                       | 2011         | 3                       | 2011–20         |
| Annualized Value of Reduced Medical Care Costs Incurred for Patients Immunized.      | \$710 .....                                       | \$355 .....                                       | \$1,420 .....                                     | 2011         | 7                       | 2011–20         |
|  | \$710 .....                                       | \$355 .....                                       | \$1,420 .....                                     | 2011         | 3                       | 2011–20         |
| <b>Costs</b>   |   |   |   |              |                         |                 |
| Annual Monetized Costs to Medical Care Providers and Suppliers.                      | \$330 .....                                       | \$165 .....                                       | \$660 .....                                       | 2011         | 7                       | 2011–20         |
|  | \$330 .....                                       | \$165 .....                                       | \$660 .....                                       | 2011         | 3                       | 2011–20         |
| <b>Transfers</b>   |   |   |   |              |                         |                 |
| Annualized Payments to Medical Care Providers and Suppliers by Federal Government.   | (\$380) .....                                     | (\$190) .....                                     | (\$760) .....                                     | 2011         | 7                       | 2011–20         |
|  | (\$380) .....                                     | (\$190) .....                                     | (\$760) .....                                     | 2011         | 3                       | 2011–20         |

\* The 6-month influenza season begins each fall and ends the next spring, thus falling in two calendar years. The first season covered by this proposed rule begins in the fall of 2011.

## VII. Regulatory Flexibility Act (RFA)

The RFA (15 U.S.C. 603(a)), as modified by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104–121), requires agencies to determine whether proposed or final rules would have a significant economic impact on a substantial number of small entities and, if so, to prepare a Regulatory Flexibility Analysis and to identify in the notice of proposed rulemaking or final rulemaking any regulatory options that could mitigate the impact of the proposed regulation on small businesses. For purposes of the RFA, small entities include businesses that are small as determined by size standards issued by the Small Business Administration, nonprofit organizations, and small governmental jurisdictions. Individuals and States are not included in the definition of a small entity.

For purposes of the RFA, we normally assume that all of the entities affected by Medicare-related rules are small, either by virtue of size or nonprofit status. As indicated in the analysis that follows, we estimate that most affected entities would incur costs of only a few thousand dollars a year. In the case of hospitals, costs would be somewhat higher but would vary primarily with patient caseload. The average per patient cost we estimate for provider costs (approximately \$26) is only about one fourth of one percent of the average hospital cost per stay (approximately \$10,000). On July 19, 2010, the Department of the Treasury, Department of Labor, and Department of Health and Human Services, published a rule in the **Federal Register** (75 FR 41726) entitled, “Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act,” which mandated that health plans in the individual and group health insurance markets cover a number of preventive services, including influenza vaccination, at no copayment or coinsurance cost to patients. In practice, this means that these plans must pay providers and suppliers for providing such vaccinations. We also have information that in the group health market virtually all health plans already paid providers and suppliers for influenza vaccination (John Hunsaker *et al.*, “Health Insurance Plans and Immunization: Assessment of Practices and Policies, 2005 through 2008,” *Pediatrics*, V. 124, December 2009). In general, insurance payments to providers and suppliers approximate the cost of vaccination and may in many

situations, such as those addressed by this proposed rule, be higher.

As a result, we do not believe that this rule would have a significant economic impact on a substantial number of small entities, and we certify that an Initial Regulatory Flexibility Analysis is not required. In the particular case of Federally qualified health centers, used by many uninsured patients, average per patient costs are only about \$600 annually, and \$26 represents about a 1 percent increase in patient costs assuming that one-fifth of all patients would be vaccinated above baseline levels (these centers are already encouraged and able to provide influenza vaccine to their patients). While this amount is substantial, it is not close to the 3 to 4 percent cost increase that HHS normally uses as the threshold of economic significance for RFA purposes if these providers had to absorb this cost. Both RHCs and FQHCs operate, moreover, under a reimbursement scheme called “All Inclusive Reimbursement Rate” (AIRR) under which Medicare and Medicaid pay for all covered services. Since vaccinations against influenza are covered under both programs, the AIRR rates should, over the period of time needed for adjustments, soon cover all costs of vaccination related to Medicare and Medicaid patients, who are about one half of the total caseload for these provider types. These conclusions would remain valid even if provider costs were twice as high as those we estimate (as discussed previously in the analysis, these costs are low compared to many estimates in the literature because all patients covered by this rule are already in provider facilities and we estimate only marginal costs). In summary, we believe that the proposed rule will have little or no consequential adverse impact on provider costs, net of insurance reimbursement. We further note that there will be little or no adverse impact on insurance companies, since they will recover any cost increases through minor rate adjustments, and the costs we estimate are negligible in proportion to industry revenues (further, we believe that few affected insurance firms are small entities as defined in the RFA). Ultimately, all of these costs will be borne by the workers or taxpayers who pay insurance premiums. We welcome comments on these estimates and conclusions.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to

the provisions of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We do not believe a regulatory impact analysis is required here because, for the reasons stated above, this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

## VIII. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$136 million. This proposed rule would impose no mandates on State, local, or Tribal governments in the aggregate. It would, however, impose gross costs of approximately \$330 million annually on affected providers and suppliers, largely offset by third party payments (including grants-in-aid), and would, therefore, approach this threshold. Because of Medicare and Medicaid coverage of influenza vaccines and vaccine administration cost, and the predominant coverage of these costs by private plans, a rough estimate would be that in the first year almost all vaccine costs and at least one half of all other costs—\$240 million or more—would be reimbursed through third party payments, leaving a net cost impact on providers of approximately \$90 million. In future years as payment benchmarks were adjusted we would expect provider costs to drop further. Accordingly, we do not believe that this proposed rule requires analysis under UMRA. Regardless, the analysis we have prepared meets the requirements of UMRA.

## IX. Federalism

Executive Order 13132 on Federalism establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that this proposed rule would not significantly affect the rights, roles, or responsibilities of the States. This proposed rule would not impose substantial direct requirement costs on State or local governments,

preempt State law, or otherwise implicate federalism.

#### List of Subjects

##### 42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

##### 42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

##### 42 CFR Part 491

Grant programs—health, Health facilities, Medicaid, Medicare Reporting and recordkeeping requirements, Rural areas.

##### 42 CFR Part 494

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

#### **PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS**

1. The authority citation for part 482 continues to read as follows:

**Authority:** Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

#### **Subpart C—Basic Hospital Functions**

2. In § 482.42, a new paragraph (c) is added to read as follows:

##### **§ 482.42 Condition of participation: Infection control.**

\* \* \* \* \*

(c) *Standard: Influenza vaccinations.*

(1) The hospital must develop and implement policies and procedures regarding administration of annual and pandemic influenza vaccinations. Pandemic procedures are to be implemented when a pandemic event is announced by the Secretary.

(2) The hospital's policies and procedures must take into account, and reflect reasonable consideration of, the recommendations in guidelines established by nationally recognized organizations (including, but not limited to, guidelines addressing patients for whom vaccination may be prioritized or temporarily contraindicated).

(3) Within its policies and procedures, the hospital must ensure all of the following, subject to the reasonable availability of vaccine and where appropriate taking into account the condition of particular patients:

(i) Before receiving the influenza vaccination, each patient, or, where appropriate, the patient's representative or surrogate (as allowed under State law), receives education regarding the benefits, risks, and potential side effects of the vaccine.

(ii) Each patient is offered an influenza vaccination annually, from the time the vaccine is available on or after September 1 through the end of February of the following year, except when such vaccination is medically contraindicated or when the patient has already been vaccinated during this time period.

(iii) The patient, or, where appropriate, the patient's representative or surrogate, has the opportunity to decline vaccination.

(iv) The patient's health record includes documentation that indicates, at a minimum, the following:

(A) The date the patient, or the patient's representative or surrogate, was provided education regarding the benefits, risks, and potential side effects of influenza vaccination.

(B) The date the patient either received the influenza vaccination or did not receive the influenza vaccination due to medical contraindications, previous influenza vaccination during the time period, or patient refusal.

#### **PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS**

3. The authority citation for part 485 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

#### **Subpart F—Conditions of Participation—Critical Access Hospitals (CAHs)**

4. Section 485.635 is amended by—

A. Redesignating paragraphs (b) through (f) as paragraphs (c) through (g), respectively.

B. Adding a new paragraph (b).

The revisions and additions read as follows:

##### **§ 485.635 Condition of participation: Provision of services.**

\* \* \* \* \*

(b) *Standard: Influenza vaccinations.*

(1) The CAH must develop and implement policies and procedures regarding administration of annual and pandemic influenza vaccinations. Pandemic procedures are to be implemented when a pandemic event is announced by the Secretary.

(2) The CAH's policies and procedures must take into account, and

reflect reasonable consideration of, the recommendations in guidelines established by nationally recognized organizations (including, but not limited to, guidelines addressing patients for whom vaccination may be prioritized or temporarily contraindicated).

(3) Within its policies and procedures, the CAH must ensure all of the following, subject to the reasonable availability of vaccine and where appropriate taking into account the condition of particular patients:

(i) Before receiving the influenza vaccination, each patient, or, where appropriate, the patient's representative or surrogate (as allowed under State law), receives education regarding the benefits, risks, and potential side effects of the vaccine.

(ii) Each patient is offered an influenza vaccination annually, from the time the vaccine is available on or after September 1 through the end of February of the following year, except when such vaccination is medically contraindicated or when the patient has already been vaccinated during this time period.

(iii) The date the patient, or, where appropriate, the patient's representative or surrogate, has the opportunity to decline vaccination.

(iv) The patient's health record includes documentation that indicates, at a minimum, the following:

(A) The date the patient, or the patient's representative or surrogate, was provided education regarding the benefits, risks, and potential side effects of influenza vaccination.

(B) The date the patient either received the influenza vaccination or did not receive the influenza vaccination due to medical contraindications, previous influenza vaccination during the time period, or patient refusal.

\* \* \* \* \*

#### **PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES**

5. The authority citation for part 491 continues to read as follows:

**Authority:** Sec. 1102 of the Social Security Act (42 U.S.C. 1302); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

#### **Subpart A—Rural Health Clinics: Conditions for Certification; and FQHC Conditions for Coverage**

6. Section 491.9 is amended by—

A. Redesignating paragraph (d) as paragraph (e).

B. Adding a new paragraph (d).

The revisions and additions read as follows:

**§ 491.9 Provision of services.**

\* \* \* \* \*

*(d) Standard: Influenza vaccinations.*

(1) The clinic or center must develop and implement policies and procedures regarding administration of annual and pandemic influenza vaccination.

Pandemic procedures are implemented when a pandemic event is announced by the Secretary.

(2) The clinic or center's policies and procedures must take into account, and reflect reasonable consideration of, the recommendations in guidelines established by nationally recognized organizations (including, but not limited to, guidelines addressing patients for whom vaccination may be prioritized or temporarily contraindicated).

(3) Within its policies and procedures, the clinic or center must ensure all of the following, subject to the reasonable availability of vaccine and where appropriate taking into account the condition of particular patients:

(i) Before receiving the influenza vaccination, each patient, or, where appropriate, the patient's representative or surrogate (as allowed under State law), receives education regarding the benefits, risks, and potential side effects of the vaccine.

(ii) Each patient is offered an influenza vaccination annually, from the time the vaccine is available on or after September 1 through the end of February of the following year, except when such vaccination is medically contraindicated or when the patient has already been vaccinated during this time period.

(iii) The patient, or, where appropriate, the patient's representative or surrogate, has the opportunity to decline vaccination.

(iv) The patient's health record includes documentation that indicates, at a minimum, the following:

(A) The date the patient, or the patient's representative or surrogate, was provided education regarding the benefits, risks, and potential side effects of influenza vaccination; and

(B) The date the patient either received the influenza vaccination or did not receive the influenza vaccination due to medical contraindications, previous influenza vaccination during the time period, or patient refusal.

\* \* \* \* \*

**PART 494—CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES**

7. The authority citation for part 494 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

**Subpart B—Patient Safety**

8. Section 494.30 is amended by adding a new paragraph (d) to read as follows:

**§ 494.30 Condition: Infection control.**

\* \* \* \* \*

*(d) Standard: Influenza vaccinations.*

(1) The ESRD facility must develop and implement policies and procedures regarding administration of annual and pandemic influenza vaccinations. Pandemic procedures are implemented when a pandemic event is announced by the Secretary.

(2) The ESRD facility's policies and procedures must take into account, and reflect reasonable consideration of, the recommendations in guidelines established by nationally recognized organizations (including, but not limited to, guidelines addressing patients for whom vaccination may be prioritized or temporarily contraindicated).

(3) Within its policies and procedures, the ESRD facility must ensure all of the following, subject to the reasonable availability of vaccine and where appropriate taking into account the condition of particular patients:

(i) Before receiving the influenza vaccination, each patient, or, where appropriate, the patient's representative or surrogate (as allowed under State

law), receives education regarding the benefits, risks, and potential side effects of the vaccine.

(ii) Each patient is offered an influenza vaccination annually, from the time the vaccine is available on or after September 1 through the end of February of the following year, except when such vaccination is medically contraindicated or when the patient has already been vaccinated during this time period.

(iii) The patient, or, where appropriate, the patient's representative or surrogate, has the opportunity to decline vaccination.

(iv) The patient's health record includes documentation that indicates, at a minimum, the following:

(A) The date the patient, or the patient's representative or surrogate, was provided education regarding the benefits, risks, and potential side effects of influenza vaccination; and

(B) The date the patient either received the influenza vaccination or did not receive the influenza vaccination due to medical contraindications, previous influenza vaccination during the time period, or patient refusal.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.) (Catalog of Federal Domestic Assistance Program No. 93.773, Medical Assistance Program.)

Dated: September 3, 2010.

**Donald M. Berwick,**  
*Administrator, Centers for Medicare & Medicaid Services.*

Approved: February 25, 2011.

**Kathleen Sebelius,**  
*Secretary.*

**Editorial Note:** This document was received in the Office of the Federal Register on April 27, 2011.

[FR Doc. 2011–10646 Filed 4–29–11; 11:15 am]

**BILLING CODE 4120-01-P**