

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Part 483****[CMS-3198-F]****RIN 0938-AN95****Medicare and Medicaid Programs; Condition of Participation: Immunization Standard for Long Term Care Facilities****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Final rule.

SUMMARY: The goal of this final rule is to increase immunization rates in Medicare and Medicaid participating long term care (LTC) facilities by requiring LTC facilities to offer each resident immunization against influenza annually, as well as lifetime immunization against pneumococcal disease. LTC facilities will be required to ensure that before offering the immunization, each resident or the resident's legal representative receives education regarding the benefits and potential side effects of immunization. The facilities will be required to offer immunization against influenza annually and immunization against pneumococcal disease once, unless medically contraindicated or the resident or the resident's legal representative refuses immunization. Increasing the use of Medicare-funded preventive services is a goal of both CMS and the Centers for Disease Control and Prevention (CDC). This final rule is intended to increase the number of elderly receiving influenza and pneumococcal immunization and decrease the morbidity and mortality rate from influenza and pneumococcal diseases.

DATES: *Effective Date:* These regulations are effective on October 7, 2005.

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SUPPLEMENTARY INFORMATION:**I. Background****A. General**

The CDC's Advisory Committee on Immunization Practices (ACIP) reported on May 28, 2004 (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5306a1.htm>) that epidemics of influenza have been responsible for an average of approximately 36,000 deaths

per year in the United States between 1990 and 1999. There is an added danger when it comes to people age 65 or older or with high risk conditions such as individuals residing in long term care facilities. In 2002, ACIP estimated the rates of influenza related hospitalization as 392 to 635 per 100,000 among adults with one or more high risk conditions, compared to 13 to 33 per 100,000 among those without high risk conditions.

According to the CDC, influenza and invasive pneumococcal disease kill more people in the United States each year than all other vaccine-preventable diseases combined. Influenza and pneumonia combined represent the fifth leading cause of death in the elderly. Immunization is the primary method for preventing invasive pneumococcal disease as well as influenza and its more severe complications. In 2002, the ACIP reported that the primary target group for influenza vaccination includes persons who are at high risk for serious complications from influenza, including approximately 35 million persons who are more than 65 years of age and approximately 33 to 39 million persons less than 65 years of age who have chronic underlying medical conditions. ACIP recommends that all residents of long term care facilities should be assessed for their needs for pneumococcal polysaccharide vaccine (PPV) and that people 65 or older, as well as persons less than 65 who have chronic illness or who are living in long term care facilities, receive the immunization, if eligible.

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 individuals are not receiving influenza and pneumococcal vaccines.

Section 4107 of the Balanced Budget Act of 1997 extended the influenza and pneumococcal immunization 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 and pneumococcal immunizations was increased under this legislation, rates of immunization did not improve as anticipated.

On April 30, 1999, the CDC and CMS entered into an interagency agreement (IA 99-87) to establish a program of collaboration between the two agencies to enhance assessment of health status and delivery of preventive services to beneficiaries of the Medicare program.

One of the initial areas highlighted for collaboration was improving influenza and pneumococcal immunization coverage through "standing orders" for those populations and settings designated as appropriate by the ACIP.

A March 24, 2000 ACIP report, which includes implementation guidelines, recommended the use of standing orders programs in both outpatient and inpatient settings to increase the number of individuals who receive the influenza vaccine. See implementation guidelines at (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4901a1.htm>). On October 2, 2002, (67 FR 61808) CMS published a final rule with comment period that removed the physician order requirement for influenza and pneumococcal vaccinations from the Conditions of Participation (CoPs) for Medicare and Medicaid participating hospitals, (LTC) facilities, and home health agencies (HHAs). The final rule was effective as of its publication date. Although the CoPs for these provider types require a physician's order for drugs and biologicals that must be signed by the practitioner responsible for the care of the patient or resident, the CoPs make an exception for influenza and PPV. These vaccines can now be administered per a physician-approved facility or agency policy, following assessment of the patient or resident for contraindications. The final rule was a major step towards increasing the immunization rates in the LTC population. To date, however, we do not have data on the specific immunization rates of nursing facility residents following the effective date of the final rule.

The Medicare Current Beneficiary Survey (MCBS) data shows that the rate of influenza vaccination of individuals age 65 and older was 70.4 percent in the year 2000, 67.4 percent in 2001, 69 percent in 2002 and 70.4 percent in 2003. MCBS data for pneumococcal vaccination for individuals age 65 and older was 62.7 percent in 2000, 63.3 percent in 2001, 64.6 percent in 2002 and 66.4 percent in 2003. Nursing facility residents are included in these figures. These rates demonstrate the need to implement strategies to help achieve, the goal set by the Department of Health and Human Service's (DHHS) Healthy People 2010 campaign. The Department's goal in this campaign is to increase the rate of influenza and pneumococcal vaccination of adults aged 65 years and older to 90 percent. Further information on preventive services, like immunizations, are available at the healthy aging site at <http://www.cms.hhs.gov/healthyaging/>

2a.asp and at <http://www.healthypeople.gov/>.

B. Influenza Incidence and Prevention

Numerous studies referenced by the CDC on the Morbidity and Mortality Weekly Report (MMWR) Web site show that—(1) persons 65 years and older are at high risk of contracting influenza; (2) they are more likely than the general population to need hospitalization or to die from complications of influenza; and (3) immunizations are effective in preventing influenza and its complications in this population (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5306a1.htm>).

In the May 2004 MMWR referenced above, the ACIP stated that while rates of influenza infection are high among children, rates of serious illness and death are highest among persons aged ≥65 years and persons of any age who have medical conditions that place them at increased risk for complications from influenza. According to ACIP, the primary target groups recommended for annual vaccination are as follows: (1) Persons at increased risk for influenza-related complications (for example, those aged ≥65 years and persons of any age with certain chronic medical conditions); (2) persons aged 50 to 64 years (because this group has an elevated prevalence of certain chronic medical conditions); and (3) persons who live with or care for persons at high risk (for example, health-care workers and individuals within a household who have frequent contact with persons at high risk and who can transmit influenza to those persons at high risk).

The ACIP report states that vaccination is associated with reductions in the following: influenza-related respiratory illness and physician visits among all age groups, hospitalization and death among persons at high risk, otitis media among children, and work absenteeism among adults. Although influenza vaccination levels increased substantially during the 1990s, further improvements in vaccine coverage levels are needed. Influenza vaccination remains the cornerstone for the control and treatment of influenza. (MMWR: Recommendations and Reports May 28, 2004/53 (RR06); 1–40 <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5306a1.htm>).

Although influenza affects persons of all ages, the CDC has identified several groups who are at increased risk for complications. One such group is comprised of residents of nursing homes or other long-term care facilities. An article in *American Family Physician*, January 1, 2002 titled, “Influenza in the Nursing Home,” notes that during

influenza epidemics, mortality rates among nursing home residents often exceed 5 percent of the nursing home population in the country. To lessen the impact of this infectious disease, the CDC recommends the influenza vaccine as the primary way of preventing the illness and its complications (<http://www.aafp.org/afp/20020101/75.html>).

On September 28, 2004, the Director of Health Care-Public Health Issues for the General Accountability Office (GAO) testified before the United States Senate Special Committee on Aging concerning a 2004 GAO study titled, “Infectious Disease Preparedness: Federal Challenges in Responding to Influenza Outbreaks” (<http://www.gao.gov/new.items/d041100t.pdf>). The Director of GAO stated that the study was conducted to identify the challenges in preventing the spread of the influenza virus because influenza is associated with an average of 36,000 deaths and more than 200,000 hospitalizations each year in the United States. Furthermore, nine out of ten persons who die from influenza and one out of two who are hospitalized due to influenza are age 65 or older. The GAO was asked to conduct the study to assess issues related to supply, demand, and distribution of vaccine during a typical flu season and to assess the Federal plan to respond to an influenza pandemic. The study was based on a survey of physician group practices, interviews with health department officials in all 50 states, as well as information about CDC activities in the 2003–04 flu season. The GAO found that the most effective way to prevent influenza is by immunizing individuals against influenza every fall season.

The 2004 ACIP recommendations referenced earlier note that influenza vaccine effectiveness varies in the elderly; however, influenza vaccine is still effective at preventing severe illness, secondary complications, and death. In the elderly population residing in nursing homes, the vaccine can be 50–60 percent effective in preventing hospitalization or pneumonia and 80 percent effective in preventing death, even though the effectiveness in preventing influenza illness often ranges from 30 percent to 40 percent.

According to the January 1, 2002 article in *American Family Physician* referenced earlier, a number of studies have also shown that nursing homes with high rates of vaccinated residents have fewer outbreaks of influenza than nursing homes with lower vaccination rates. The article further states that many studies have shown that influenza vaccination of nursing home residents and staff can significantly decrease rates

of hospitalization, pneumonia, and related mortality. Therefore, it is vital to the well-being of the residents of nursing homes that they are offered immunization if not medically contraindicated, and that facilities ensure residents receive the immunizations at the appropriate time to prevent the spread of the influenza virus if not refused by the resident or the resident's representative.

The February 14, 2005, article in the *Archives of Internal Medicine* titled “Impact of Influenza Vaccination on Seasonal Mortality in the U.S. Elderly Population” reports the results of the study conducted by Lone Simonsen and colleagues on flu vaccination rates among the elderly population (<http://archinte.ama-assn.org/cgi/content/abstract/165/3/265>). This study reports that vaccination of the elderly population against influenza may be less effective in preventing death among the elderly than previously estimated. A joint CDC and National Institutes of Health (NIH) press release (February 15, 2005), (<http://www.cdc.gov/flu/pdf/statements/dmortality.pdf>), stated that the Simonsen, *et al.* study did not show that the flu vaccine is ineffective at protecting the elderly from influenza. Rather, the study indicated that different research approaches result in different estimates of influenza vaccine effectiveness at preventing death among the elderly.

The Simonsen, *et al.*, study does not imply that the elderly should not receive influenza vaccine. Furthermore, we note that this study addresses the elderly population as a whole, and does not analyze the more vulnerable group of nursing home residents addressed by this regulation and the studies of those residents summarized later in this preamble. The conclusions in the study are in contrast to most other peer-reviewed studies that address the same issue (See for example, JAMA; Chicago; Oct 22–Oct 29 1997; 278; 16; Jane E Sisk; Alan J Moskowitz; William Whang; Jean D Lin. *et al.*). The CDC and ACIP continually review their influenza vaccine recommendations as well as published research in order to develop the best recommendations for protecting all Americans from influenza.

The study is a reminder that there is room for improvement in how we protect the elderly from influenza, and the CDC and NIH encourage research that strengthens our ability to do so. The study conducted by the CDC and published in the *Journal of American Medical Association* (JAMA), “Impact of Influenza Vaccination on Seasonal Mortality in the U.S. Elderly Population” by Simonsen *et al.*,

September 2005, looked at hospital data from 1961 to 2001 and found an overall increasing trend in the number of flu-related hospitalizations in the United States each year, despite the fact that the number of immunizations for influenza has increased. The CDC has provided the following information to explain this phenomenon:

1. The range of illnesses analyzed in the new study is broader than in the previous study. The new study includes respiratory and heart diseases associated with influenza infections. The earlier CDC study published in 2000 analyzed only pneumonia and influenza hospitalizations. When analyses were restricted to pneumonia and influenza hospitalizations, however, there was still an increase in hospitalizations.

2. Influenza A (H3N2) viruses predominated in several recent influenza seasons, and these viruses generally have been associated with higher numbers of serious illnesses than influenza A (H1N1) or influenza B viruses. The higher numbers of people hospitalized during H3N2 influenza seasons may have increased the average.

3. The U.S. population is growing older and therefore, more vulnerable to developing severe complications from influenza.

4. During the 1990s influenza viruses have either circulated or been detected for longer periods of time. (<http://www.cdc.gov/flu/about/qa/hospital.htm>). The CDC also provided additional information to help put the study in context.

- The Simonsen et al. study does not show that the flu vaccine is ineffective at protecting the elderly from influenza. Rather, the study indicates that different research approaches result in different estimates of influenza vaccine effectiveness at preventing death among the elderly.

- The Simonsen study has some significant limitations when it comes to assessing the effectiveness of influenza vaccination.

- The study analyzes patterns of influenza vaccination and death among the elderly from 1961 to 2001 and suggests a relationship between the two. This type of analysis is called an "ecologic study".

- Ecologic studies look at overall trends and do not include information on specific individuals, such as vaccination status and health conditions.

- Since there is no information on which of the individuals who died were vaccinated or their underlying conditions, the death and vaccination patterns identified in this study cannot be directly linked. Apparent

associations can be inferred, but may be misleading or hard to interpret.

- Many previously published "observational studies" suggest a higher level of influenza vaccine effectiveness against death in the elderly than indicated in the Simonsen paper.

- There are several types of epidemiologic studies, including ecologic studies, observational studies (for example, studies that compare vaccinated people to people who choose not to get vaccinated), and clinical trials (or experiments), where people are randomly assigned to a treatment or control group. Clinical trials provide the most reliable and valid data on vaccine effectiveness. However, conducting a true clinical trial of the effect of influenza vaccine in the elderly would be unethical, because investigators would randomly assign participants to get vaccinated or not, despite the fact that influenza vaccination has been recommended for many years for all those aged 65 and older. So, to study vaccine effectiveness researchers have observed what has happened among people who have chosen on their own to be vaccinated and those who have not (called "observational studies").

- The main weakness of observational studies is that they are likely to be influenced by selection bias (for example, if very vulnerable elderly people are less likely to get vaccinated than the relatively healthy elderly, then this bias might lead to overestimates of vaccine effectiveness for preventing deaths).

- The main strength of observational studies is that information on individuals is analyzed and factors that may bias the result can be taken into account during the analysis. For this reason, observational studies have been considered more appropriate than ecologic studies for evaluating vaccine effectiveness. For the entire CDC response to the Simonsen study see <http://www.amda.com/clinical/immunization/flustudy.htm>.

A meta-analysis of 40 years of studies performed by an international collaboration of scientists called the Cochrane Review Group was published in the British journal *The Lancet* in September 2005. The analysis found that the vaccine is only about 28 percent effective when given to people over 65. However, the researchers said that the vaccine is less effective for those elderly who live in the community and described the vaccine as "modestly effective" for elderly people in long-term care facilities. The study found that when used in nursing facilities, influenza vaccines prevented up to 42 percent of deaths from influenza and

pneumonia. They also found that for the elderly living in the community, influenza vaccination could prevent up to 30 percent of hospitalizations. Despite the results of this most recent study, influenza vaccination is still recommended by the CDC and the World Health Organization. In response to the study, a CDC spokesperson stated, "There are a number of studies published that report on varying degrees of effectiveness. But there are also a lot of studies that point to the fact that the vaccines are effective in preventing the serious complications that lead to hospitalizations and death, and that's an important note that we should never lose sight of. If I had a loved one who was in the high risk group, I would strongly recommend they get vaccinated." Further, William Schaffner, who heads the preventive medicine department at Vanderbilt University's medical school, pointed out in the September 22, 2005 *Washington Post*, "Vaccination is not perfect, but it still is enormously beneficial. Even 30 percent effectiveness prevents a lot of suffering." We agree. See <http://www.thelancet.com/>.

The CDC continues to recommend that people aged 65 and older get vaccinated against influenza each year as persons aged 65 and older are at high risk for complications, hospitalizations, and death from influenza. In the joint press release referenced above, the CDC and National Institutes of Health (NIH) continue to support the ACIP recommendation that people aged 65 and older get vaccinated against influenza each year.

C. Pneumococcal Disease Incidence and Prevention

Like influenza, invasive pneumococcal disease is particularly prevalent and severe in those 65 years and older. This population is at high risk of contracting invasive pneumococcal disease, with a high risk of resultant complications, hospitalizations, and deaths. Pneumococcal immunizations are effective in preventing pneumococcal disease in this population.

According to CDC's Active Bacterial Core Surveillance for pneumococcal disease, approximately 5,700 deaths from invasive pneumococcal disease (bacteremia and meningitis) are estimated to have occurred in the United States in 2002 (<http://www.cdc.gov/ncidod/dbmd/abcs/survreports/spneu02.pdf>). An article in the *American Journal of Preventive Medicine*, August 2003, titled "Standards for Adult Immunization Practices," notes that overall, vaccine

effectiveness against invasive pneumococcal disease among immunocompetent people aged 65 years is 75 percent. Based on 1998 projections, annually, 76 percent of invasive pneumococcal disease cases and 87 percent of resulting deaths occurred in people who were eligible for pneumococcal vaccine in the United States. (http://www.cdc.gov/nip/recs/rev_stds_adult_AJPM.pdf).

The ACIP and CDC recommend immunization for pneumococcal disease for those 65 years old or older, and for people with a serious long-term health problem, such as heart disease, diabetes, or immunosuppression due to disease, organ transplantation, or medical treatment such as chemotherapy. The American Lung Association warns that people considered at high risk for invasive pneumococcal disease include the elderly, the very young, and those with underlying health problems, such as chronic obstructive pulmonary disease (COPD). Patients with diseases that impair the immune system, such as AIDS, or patients with other chronic illnesses, such as asthma, or those undergoing cancer therapy or organ transplantation, are particularly vulnerable.

According to CDC recommendations, usually one dose of the PPV is all that is needed to prevent pneumococcal disease or a person only needs to be immunized once in a lifetime. However, a second dose is recommended for people 65 and older who received their first dose prior to 65 years of age, if five or more years have passed since that dose. A second dose is also recommended for people with a damaged spleen or without a spleen, sickle-cell disease, HIV infection or AIDS, cancer, leukemia, lymphoma, multiple myeloma, kidney failure or nephrotic syndrome, an organ or bone marrow transplant, or who are taking medication that lowers immunity (such as chemotherapy or long-term steroids).

Accordingly, we believe it vital that facilities secure the consent of their residents or legal representative for vaccination and provide their residents with vaccinations. Educating residents about the advantages of being vaccinated allows residents to understand the benefits of pneumococcal vaccines. The 1997 ACIP recommendations state that, "Pneumococcal polysaccharide vaccine generally is considered safe based on clinical experience since 1977, when the pneumococcal polysaccharide vaccine was licensed in the United States. Approximately half of the persons who receive pneumococcal vaccine develop mild, local side effects

(for example, pain at the injection site, erythema, and swelling). These reactions usually persist for less than 48 hours. Moderate systemic reactions (for example, fever and myalgias) and more severe local reactions (for example, local induration) are rare. Severe systemic adverse effects (for example, anaphylactic reactions) rarely have been reported after administration of pneumococcal vaccine. In a recent meta-analysis of nine randomized controlled trials of pneumococcal vaccine efficacy, local reactions were observed among approximately one third or fewer of 7,531 patients receiving the vaccine, and there were no reports of severe febrile or anaphylactic reactions." The 1997 ACIP recommendations further stated that pneumococcal vaccination has not been causally associated with death among vaccine recipients. Additional information about precautions and contraindications can be obtained from the CDC. The vaccine manufacturer's package insert may also be reviewed for more information. See: (<http://www.cdc.gov/mmwr/preview/mmwrhtml/00047135.htm#00002349.htm>).

CDC's March 24, 2000 MMWR states that in recent years, a rapid emergence of antimicrobial resistance among pneumococci, especially to penicillin, has occurred. Increasing pneumococcal vaccination rates could help prevent invasive pneumococcal disease caused by vaccine-type, multidrug-resistant pneumococci. Outbreaks of pneumococcal disease caused by a single drug resistant pneumococcal serotype have occurred in institutional settings, including nursing homes. The same MMWR report notes that in 1999, because of concerns about pneumococcal antimicrobial resistance and under use of pneumococcal vaccine, the American Medical Association and several partner organizations issued a Quality Care Alert that supports ACIP's recommendations for pneumococcal vaccination. (Use of Standing Orders Programs to Increase Adult Vaccination Rates: MMWR 2000/49 RR01 15–26 March 24).

A CMS/CDC report, "Respiratory Disease Burden in Nursing Homes" (http://www.nationalpneumonia.org/sop/RDBNH_INTERIMProjectRpt_1-31-03.pdf) notes that both influenza vaccine and PPV are protective to residents in nursing homes. Based on two years of analysis (multivariate/multilevel), influenza vaccine may be associated with a 27 to 35 percent reduction in mortality, and a 44 to 52 percent reduction in all-cause hospitalization. Similarly,

pneumococcal vaccination may be associated with a 20 to 26 percent reduction in mortality, and a 12 to 28 percent reduction in all-cause hospitalization in nursing home residents. The report also suggests that a facility-level influenza vaccination of 80 percent of residents may be independently associated with reduced patient hospitalization and death.

D. Why a Change in the Conditions of Participation Is Needed

In January 2000, the Department of Health and Human Services launched Healthy People 2010, a comprehensive, nationwide health promotion and disease prevention campaign. "Immunizations and Infectious Diseases" is one of the focus areas. Healthy People 2010 set the target rate for influenza and PPV vaccination of adults aged 65 years and older at 90 percent. According to CMS's Adult Immunization Project "despite the fact that influenza and pneumococcal vaccines are clinically effective, cost-effective, and are Medicare Part B covered benefits, they remain underutilized." (http://www.ofmq.com/user_uploads/National%20Immunization%20Project.pdf).

Based on the 1999 National Nursing Home Survey, only 66 percent of nursing home residents had received the influenza vaccine in the previous year and only 38 percent had ever had the pneumococcal vaccine. The October 2004 article in the American Family Physician titled "Pneumonia in Older Residents of Long-Term Care Facilities" noted that, "when compared to persons in the overall community, residents in LTC facilities have more functional disabilities and underlying medical illnesses and are at increased risk of acquiring infectious diseases" (<http://www.aafp.org/afp/20041015/1495.html>). Risk factors include unwitnessed aspiration, sedative medication, and co-morbid illnesses. Influenza-associated mortality is a major concern for persons with chronic diseases; this mortality increase is most marked in persons 65 years of age or older, with more than 90 percent of the deaths attributed to pneumonia and influenza occurring in persons of this age group.

As noted in the October 15, 2004 article, "Pneumonia in Older Residents of Long-Term Care Facilities" in the journal American Family Physician, "The number of frail older adults living in LTC facility is expected to increase dramatically over the next 30 years." (<http://www.aafp.org/afp/20041015/1495.html>). The article further states

that an estimated 40 percent of adults will spend some time in a LTC facility before dying. Unless control measures are more vigorously implemented, the number of deaths from influenza and pneumonia with respect to residents in LTC facilities and the number of consequent complications might increase significantly.

In summary, immunizations save lives and can help avoid needless suffering and unnecessary costs of complications from various infectious diseases, and, as many family members and health care workers know, they can prevent the spread of infection to others. However, despite the availability of safe and effective vaccines, substantial portions of susceptible adults are not being immunized. To reduce morbidity and mortality rates, delivering appropriate vaccinations in a timely manner is vital. This rule is expected to facilitate the delivery of appropriate vaccinations to residents in LTC facilities in a timely manner and increase vaccination rates, thereby decreasing the morbidity and mortality rate of influenza and pneumococcal diseases in this population. This rule also has the potential to reduce overall healthcare costs by reducing the need for the treatment of influenza and pneumococcal diseases and their complications.

E. Immunizations and LTC Facilities

According to a June 2002 CDC summary of the National Nursing Home Survey, 46,000 nursing home residents (2.5 percent) had pneumonia in 1999. The average length of stay in a LTC facility for a resident with pneumonia as the primary diagnosis was 124 days in 1999 (http://www.cdc.gov/nchs/data/series/sr_13/sr13_152.pdf).

A November 2000 article in the journal *Infection Control and Hospital Epidemiology* titled "Increasing Pneumococcal Vaccination Rates Among Residents of Long-Term Care Facilities," noted that there were 1,590,763 individuals over 65 years of age residing in LTC facilities in the United States in 1990, and the number is estimated to grow to 2.9 million by 2020 (*Infection Control and Hospital Epidemiology*, Volume 21 (11) (705–710) November 2000). A substantial increase in vaccination rates among such a large population will decrease the number of cases of influenza and pneumococcal bacteremia and related death.

A 1999 RAND report stated that the proportion of the U.S. population over age 65 had increased from 5 percent in 1900 to 13 percent in 1997. This change in demographics, combined with an

increase in average life expectancy, has highlighted the importance of preventive care services for older individuals. The October 1997 Journal of the American Medical Association (JAMA) article "Cost-Effectiveness of Vaccination Against Pneumococcal Bacteremia Among Elderly People" indicated that vaccination of elderly people against pneumococcal bacteremia is one of the few interventions that have been found to both improve health and save medical costs. Vaccination both reduced medical expenses and improved health for the overall age group of 65 years and older (JAMA; Chicago; Oct 22–Oct 29 1997; 278; 16; Jane E Sisk; Alan J Moskowitz; William Whang; Jean D Lin et al). The article further noted "Vaccination of the 23 million elderly people unvaccinated in 1993 would have gained about 78,000 years of healthy life and saved \$194 million."

Overall, the literature supports increasing pneumococcal immunizations. Pneumococcal vaccination saves health care dollars by preventing bacteremia alone and is greatly underused among the elderly population. These results support both recent recommendations of the ACIP as well as public and private efforts to increase vaccination rates.

F. Vaccine Shortages

In the Fall of 2004, there was a major shortage of inactivated influenza vaccine in the United States. One of the major manufacturers of the influenza vaccine informed the CDC in early October 2004 that none of its flu vaccine would be available for distribution in the United States. Because of the shortage, Federal health officials released new guidelines as to whom should receive a flu vaccine, describing those at high-risk of influenza-related health complications as priority groups. At that time, the interim recommendations from the CDC stated that people 65 and older, as well as all those between the ages of 2 to 64 with chronic medical conditions and 6–23 month old children, were to be prioritized for receiving influenza vaccination. Another group deemed a priority was the population residing in nursing homes.

We understand that providers of LTC services may be concerned about how they will meet the requirements of this regulation should an influenza vaccine shortage occur in the future. The September 2, 2005 MMWR, "Update: Influenza Vaccine Supply and Recommendations for Prioritization During the 2005–06 Influenza Season," states that both influenza vaccine

distribution delays and vaccine supply shortages have occurred in the United States in three of the last five influenza seasons. In response, prioritization has been implemented in previous years to ensure that enough influenza vaccine is available for those at the highest risk for complications. In the case of a true vaccine shortage as declared by HHS, CMS would exercise its enforcement discretion by instructing the State Survey Agencies (SSAs) not to take enforcement actions against facilities that are out-of-compliance with this requirement if they were unable to obtain vaccine for their residents.

G. Requirements for Issuance of Regulations

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances.

This final rule finalizes proposed provisions set forth in the August 15, 2005 proposed rule (70 FR 47759), after considering public comments. In addition, this final rule has been published within the 3-year time limit imposed by section 902 of the MMA. Therefore, we believe that the final rule is in accordance with the Congress' intent to ensure timely publication of final regulations.

II. Provisions of the Proposed Rule

On August 15, 2005, we published a proposed rule in the **Federal Register** (70 FR 47759) to respond to the ACIP recommendations on "Prevention and Control of Influenza" (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5306a1.htm>), as well as to promote the DHHS Healthy People 2010 goals for increasing immunization rates. Specifically, the ACIP outlined the requirements for a successful vaccination program including combined publicity and education for health-care workers and other potential vaccine recipients; a plan for identifying persons at high risk; and efforts to remove administrative and financial barriers that prevent persons from receiving the vaccines, including use of

standing orders programs. Based on the ACIP recommendation, we proposed the following requirements for LTC facilities at § 483.25(n):

- Require LTC facilities to offer each resident immunization against influenza October 1 through March 31 annually, and facilities must also offer (without a specified timeframe) lifetime immunization against pneumococcal disease. A second immunization may be given under certain circumstances.
- Require documentation in the resident's medical record indicating the resident's influenza and pneumococcal immunization status including whether influenza and pneumococcal immunizations were medically contraindicated and whether the influenza and pneumococcal immunization were refused. If refused, the record must indicate that the resident or his/her representative received appropriate education and consultation.

III. Analysis of and Responses to Public Comments

We received 61 comments from individuals, physicians, nurses, hospitals, long term care facilities, health care associations, pharmacy associations and state agencies. All comments were reviewed and analyzed. After associating like comments, we placed them in categories based on subject matter. Summaries of the public comments received and our response to those comments are set forth below.

General

Many commenters supported the proposed requirements. We also received comments suggesting changes in the rule (for example, to protect residents' rights), and we received requests for clarification of various issues. In addition, some commenters said they did not believe the rule was necessary, and some commenters believed the rule could be harmful to LTC facility residents. The comments and our responses are listed below.

Comment: Many commenters supported our proposed immunization rule, which would mandate offering influenza and pneumococcal vaccines to all residents of LTC facilities. The commenters cited the major impact that both influenza and pneumococcal diseases have on LTC residents. One commenter noted, "We consider this Proposed Rule to be of critical importance to the long-term care provider community and to the recipients of nursing facility services, all of whom are entitled to the ongoing provision of optimal care and services." Another commenter supported the rule

because " * * * the prevention of influenza and pneumococcal disease is both cost effective and good practice. Simply put, it is the right thing to do!"

Response: We appreciate commenters recognizing the positive impact of immunizations on the health of LTC residents.

Comment: Some commenters stated that the influenza vaccine is contaminated with thimerosal (a vaccine preservative containing mercury), aluminum, or bacteria. One commenter stated that "until the flu shots are cleaned up (at least mercury and aluminum removed) it is madness to even administer them to long term care patients." The commenter suggested instead investing in building immunity with raw and fermented food. Another commenter mentioned the influenza vaccine that was manufactured in England in 2004 and expressed concern about future bacterial contamination of influenza vaccine.

Response: Some people believe that the mercury in thimerosal, a preservative used in some vaccines, has caused autism in children. Although researchers so far have found no evidence of a connection between the use of thimerosal in vaccines and autism, research is continuing. In 1999 at the urging of the U.S. Public Health Service and the American Academy of Pediatrics, vaccine manufacturers agreed to reduce or eliminate thimerosal in pediatric vaccines. However, the FDA requires manufacturers to include a preservative in all vaccines distributed in multi-dose vials to prevent bacterial contamination of the vaccine. Since most injectable influenza vaccine is dispensed in multi-dose vials, most influenza vaccine contains thimerosal. Nevertheless, according to the CDC, there is no convincing evidence of harm caused by the low doses of thimerosal in vaccines, except for minor reactions like redness and swelling. Pneumococcal vaccine does not contain thimerosal. Influenza and pneumococcal vaccines do not contain aluminum. The CDC points out that, "Vaccines are held to the highest safety standards."

We note that FDA found the influenza vaccine manufactured in England in 2004 to be unsuitable for use, and the vaccine never reached the market.

Comment: One commenter asks "Does anyone remember when President Ford got on TV to propagandize the masses into getting the Swine Flu vaccine?" The commenter said that lives were ruined due to Guillain-Barré Syndrome caused by a vaccine that was supposed to protect them.

Response: According to the CDC, "In 1976, swine flu vaccine was associated with a severe temporary paralytic illness called Guillain-Barré Syndrome (GBS) <http://www.cdc.gov/nip/vacsafe/concerns/gbs/default.htm>."

Influenza vaccines since then have not been clearly linked to GBS, although research suggests a small risk of the syndrome was associated with the influenza vaccines in 1992–1993 and 1993–1994. However, if there is a risk of GBS from current influenza vaccines, it is estimated at 1 or 2 cases per million persons vaccinated * * * much less than the risk of severe influenza, which can be prevented by vaccination."

Comment: A few commenters charged that the influenza vaccine can cause the flu or other illnesses and may even cause death. Some provided anecdotal information about becoming ill after receiving a flu shot or said that an elderly parent had died after receiving a flu shot. One commenter said that some individuals have experienced severe reactions after receiving more than one pneumococcal immunization. One commenter raised the issue of the "substantial injuries and medical costs that inevitably occur from mass vaccination."

Response: Both the influenza and pneumococcal vaccines are inactivated, that is, the virus in the vaccine has been killed; therefore these vaccines cannot cause influenza or pneumonia. We note that Flu Mist uses a live vaccine; however, it is not indicated for use in the elderly. The CDC has stated, "Most people who receive vaccines experience no, or only mild, reactions such as fever or soreness at the injection site. Very rarely, people experience more serious side effects, like allergic reactions * * * life-threatening allergic reactions are very rare," particularly in relation to influenza vaccines. The 1997 ACIP recommendations state that pneumococcal vaccination has not been causally associated with death among vaccine recipients. As we stated in the preamble to the proposed rule "In a meta-analysis of nine randomized controlled trials of pneumococcal vaccine efficacy, very few local reactions were observed, and there were no reports of severe febrile or anaphylactic reactions." The CDC article further states that, influenza and invasive pneumococcal disease kill more people in the United States each year than all other vaccine-preventable diseases combined. Therefore, the benefits of immunizations outweigh the small number of significant adverse effects observed after immunizations are administered.

Comment: Many commenters stated that nursing home residents must be able to refuse immunizations. One commenter said, "Seniors should not be forced to be immunized since they are free sovereign individuals who are capable of making their own decisions on such matters." Another commenter said that forced vaccination of American citizens is unconstitutional. One commenter expressed the fear that there would be reprisals against residents who refused or whose representatives refused immunization, including being refused treatment or being forced to leave the nursing home.

Response: We agree with the commenters that residents of LTC facilities have the right to refuse immunizations. In fact, the existing Conditions of Participation (CoP) at § 483.10(b)(4) state that residents of LTC facilities have the right to refuse treatment. On admission to an LTC facility, residents or their representatives are given written documentation about their right to refuse any medication or treatment. We have further emphasized this right in the text of the final rule, which states, "The resident or the resident's legal representative has the opportunity to refuse immunization." Nevertheless, the final rule requires every facility to offer immunization because a goal of the rule is to prevent the spread of preventable illness. In addition, in accordance with § 483.10(b)(4), residents have the right to refuse treatment. Therefore, facilities would not force any resident who refuses to be immunized to receive the vaccine. The benefits of immunization are evidenced in numerous studies referenced by the CDC in the Morbidity and Mortality Weekly Report (MMWR), which show that: (1) persons 65 years and older are at high risk of contracting influenza, (2) they are more likely than the general population to need hospitalization or to die from complications of influenza, and (3) immunizations are effective in preventing influenza and its complications in this population. (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5306a1.htm>).

Comment: Some commenters stated that this rule is based on "pharmaceutical company propaganda," and it is for their benefit. One commenter stated that pharmaceutical companies have a strong influence over U.S. lawmakers and that drug companies spend millions in campaign contributions. Another commenter stated that "preying upon unsuspecting seniors whose care families have entrusted to long term care facilities to the financial benefit of pharmaceutical

companies is criminal." Another commenter stated that "vaccination is the quintessential form of medical quackery in our day and age and is causing untold damage to health, wellbeing and prosperity for all except those who profit from its use."

Response: The goal of this rule is to protect the health of LTC facility residents using a proven preventive measure to stop the spread of infection and reduce morbidity and mortality. The rule is not being published based on "propaganda from pharmaceutical companies," but on data and evidence that the CDC and many other researchers have provided to the public and health care communities. The ACIP reported on May 28, 2004 that epidemics of influenza have been responsible for an average of approximately 36,000 deaths per year in the United States between 1990 and 1999. It stated that there is an added danger when it comes to people age 65 or older or with high risk conditions such as individuals residing in long term care facilities. According to the January 1, 2002 article in American Family Physician, a number of studies have also shown that nursing homes with high rates of vaccinated residents have fewer outbreaks of influenza than nursing homes with lower vaccination rates. The article further states that many studies have shown that influenza vaccination of nursing home residents and staff can significantly decrease rates of hospitalization, pneumonia, and related mortality.

Consent for immunization

Comment: Many commenters stated that before an immunization is given to a resident, informed consent must be obtained. Other commenters specified that a resident's consent should be in writing. One commenter referenced an article, "The moral right to conscientious, personal belief or philosophical exemption to mandatory vaccination laws" by Barbara Loe Fisher, (<http://www.nvic.org/Loe-Fisher/blfstmt052097.htm>) which states that "The National Vaccine Information Center has not advocated the abolishment of vaccination laws as other groups have proposed. However, we have always endorsed the right to informed consent as an overarching ethical principle in the practice of medicine for which vaccination should be no exception."

Response: We agree it is vital that facilities secure the informed consent of their residents or legal representatives for vaccinations before they are administered. Therefore, we would require that the facilities document the

resident's immunization status and related information in the resident's medical record. Moreover, we are requiring LTC facilities to ensure that before offering the immunizations, each resident or resident's representative receives education regarding the benefits and potential side effects of influenza and pneumococcal immunizations. This final rule clearly states that the resident or the resident's representative has the right to refuse the immunization.

Comment: Under the proposed rule, we would have required facilities to educate residents or their representatives about immunization only if immunization were refused. Some commenters stated that educating residents or their representatives on the risks and benefits of immunization prior to giving the immunization is important, too. One commenter said that a more effective way to educate residents is to present the information upon admission. The commenter said, "This avoids the impression that the facility is trying to talk the resident into receiving a vaccination that the resident does not want."

Response: We agree that it is important to provide education prior to immunization. Therefore, this final rule requires LTC facilities to educate all residents or resident's representation on the benefits and potential side effects of the influenza and pneumococcal vaccinations before offering immunization. At the discretion of the facility, this education can be provided at any time, including upon admission to the facility, as long as the education is provided before the immunizations are offered.

Comment: One commenter asked for clarification of the intent of the proposed requirement for "consultation" with residents who refused immunization.

Response: We proposed a requirement for education and consultation in the proposed rule if immunization is refused. This final rule does not contain a specific requirement for consultation with residents or their representatives if immunization is refused. Instead, LTC facilities are required to provide education about immunization to all residents. We removed the word "consultation" so as not to confuse facilities.

Comment: Commenters had several suggestions to ensure residents receive adequate education about the immunizations. Some commenters said we should specify that residents must receive educational information in writing.

Response: We are providing flexibility to the facilities on how they provide educational information to the residents or their representatives. It is important to note, however, that all health care providers are required by the National Childhood Vaccine Injury Act to provide vaccine information sheets (VISs) prior to immunization. These sheets contain a wealth of information. For example, the influenza VIS explains how flu is spread, the symptoms, the potential complications, what types of flu vaccines are available (including vaccines with and without the preservative thimerosal), how the vaccines work, who should be vaccinated, contraindications to vaccination, and the risk of developing a reaction (including rare but life-threatening allergic reactions and Guillain-Barre Syndrome). Single camera-ready copies of the vaccine information materials are available from State health departments. Copies are also available on the CDC Web site at <http://www.cdc.gov/nip/publications/VIS>. Copies are available in English and in other languages. Instructions for using the vaccination information sheets can be found at <http://www.cdc.gov/nip/publications/VIS/vis-instructions.txt>. Facilities may choose to use the VIS documents as a means of providing education. Note that the National Vaccine Injury Compensation program (NVICP) requires Vaccine Information Statements (VIS) be provided to patients or their legal representatives, once a vaccine is in the program and a final VIS has been developed. The NVICP provides compensation to adults as well as children for adverse events related to vaccines covered by the program. To date, pneumococcal vaccine is not in the program and although influenza vaccine is, the final VIS will not be available until approximately October.

Comment: One commenter asked for clarification of the word "consent" and stated that the Vaccine Information Sheet (VIS) can be given to the resident or his or her representative and documented in the medical record to fulfill the requirement for informed consent. Special written consent is not required for vaccination, according to the commenter.

Response: We agree that a special written consent is not necessary for vaccinations. As stated in the previous response, the National Childhood Vaccine Injury Act ("the Act") requires health care providers to provide a current, relevant vaccination information sheet (VIS) produced by the CDC prior to giving immunizations to children or adults for diphtheria, tetanus, pertussis, measles, mumps,

rubella, polio, hepatitis B, Haemophilus influenzae type b (Hib), varicella (chickenpox), or pneumococcal conjugate vaccinations (effective 12/15/02). Additionally, the Act requires health care providers to make a notation in each patient's permanent medical record at the time vaccine information materials are provided indicating: (1) The edition date of the materials distributed and (2) the date these materials were provided as per CDC's requirements.

Comment: One commenter stated that verbal discussion with the resident or the resident's representative may be a problem if the resident is cognitively impaired and the representative lives out of state or is difficult to reach.

Response: We understand that providing education prior to offering influenza and pneumococcal immunizations and obtaining consent may be difficult under some circumstances. However, as with other procedures that take place in LTC facilities, facilities should make a reasonable effort to obtain consent.

Documentation

Comment: One commenter stated that CMS should consider implementing a mechanism for residents or their representatives to indicate if they received immunizations within the recommended time frame. Another commenter stated CMS should create a system that ensures that accurate immunization information is captured.

Response: We appreciate the comment. CMS is working on adding the immunization information in the MDS 3.0 version and that will be a source to capture accurate immunization information for each resident in the nursing facility. The other elements of resident's medical record would also be a potential source for information. Another source of information would be individual State immunization registries.

Comment: One commenter pointed out that it can be difficult or impossible to obtain a complete immunization history for some LTC facility residents. The commenter said that most residents have some degree of cognitive impairment and may not be able to provide a history. Family members or friends may be unavailable or unaware of a resident's immunization history.

Response: We agree that there may be difficulties in obtaining the history of immunizations especially in the case of cognitively impaired residents. However, we expect that facilities will make reasonable efforts to obtain immunization histories for their residents.

Comment: One commenter pointed out that it can be difficult or impossible to obtain a complete immunization history for some LTC facility residents. The commenter said that most residents have some degree of cognitive impairment and may not be able to provide a history. Family members or friends may be unavailable or unaware of a resident's immunization history.

Response: We agree. This final rule does not contain language requiring LTC facilities to obtain and document complete immunization histories for all residents. However, we expect that facilities will make reasonable efforts to obtain immunization histories for their residents to avoid giving unnecessary immunizations.

Comment: A few commenters pointed out that individual facilities, must have the flexibility to develop their own protocols for immunization and their own formats for documentation. One commenter said they we should specify that the medical records of residents who are immunized should be documented with the name and lot number of the vaccine, the quantity given, the route of administration, the date, and the signature of the person who administers the vaccine.

Response: We agree that facilities must have some flexibility in implementing the requirements. The final rule dictates neither the protocols that need to be in place nor the format for documentation. However, facilities will need to be able to demonstrate to State agency surveyors that they have an immunization protocol and that they have documentation for each resident to show that they have educated residents or their representatives and offered influenza and pneumococcal immunizations. Additionally, we expect that facilities will follow standard practice and when an immunization is given, document the type of vaccine, the lot number, and other pertinent information per facility policy.

Vaccine Availability

Comment: Some commenters stated that the final rule should indicate that if a shortage or substantial delay in vaccine supply occurs, SNFs and nursing homes will be automatically exempt from compliance with this CoP during the shortage period.

Response: We understand that providers of LTC services are concerned about meeting the requirements of this regulation if an influenza vaccine shortage occurs in the future. In the case of a vaccine shortage as declared by HHS or documented local or regional shortages, CMS could exercise its enforcement discretion by instructing

State Survey Agencies (SSAs) not to take enforcement action against LTC facilities that are out of compliance with this requirement if the facilities were unable to obtain vaccine for their residents. We do not agree that the final rule should include an exemption for all LTC facilities, because situations and vaccine availability may vary across the country. We expect that the SSA would need to verify that a facility was unable to meet the requirement due to a shortage before determining that enforcement action was not warranted.

Comment: One commenter said that CMS regards a vaccine shortage as the only relevant variable in exercising enforcement discretion to alter its mandated immunization of LTC residents. The commenter argued that a mandate to immunize a target population annually is not an essential feature of a responsible flu prevention and control strategy because a new influenza prevention and control strategy must be tailored to the distinctive characteristics of each year's influenza strain; the types, effectiveness, and availability of potential preventive and other interventions; and other practical and ethical considerations. The commenter said that, in some years, there might be a better way to protect LTC residents from influenza than achieving a target vaccination rate. Further, there might be another subgroup for which access to the influenza vaccine is more scientifically and ethically justified.

Response: We agree that each new flu season presents a challenge in terms of how best to prevent and control the spread of influenza throughout the U.S. population. We will carefully consider CDC's annual guidance on an ongoing basis to determine whether to exercise our enforcement discretion for reasons other than a vaccine shortage. In addition, in contemplating future rulemaking, we will consider whether there are additional interventions that facilities should put into place to protect their residents from influenza.

Staff Immunization

Comment: A few commenters stated that staff in LTC facilities need to be immunized. One commenter pointed out that emerging data indicate that the best protection for the LTC population is to prevent exposure by immunizing health care providers and visitors to the facilities.

Response: We agree that it is very important for health care workers to be immunized. In fact, CMS conditions of participation (CoPs) for nursing facilities (NFs) at 42 CFR 483.65 require nursing facilities (NF) to establish and

maintain an infection control program designed to prevent the development and transmission of disease and infection. The CDC recommends that all health care workers be immunized annually. The Occupational Safety and Health Administration (OSHA) strongly supports the CDC guidelines for immunization of health care workers. OSHA's mission is to assure the safety and health of America's workers by setting and enforcing standards; providing training, outreach, and education; establishing partnerships; and encouraging continual improvement in workplace safety and health. OSHA has placed links to the CDC guidelines on immunization on the OSHA Web site at <http://www.cdc.gov/flu/professionals/vaccination/hcw.htm> and <http://www.cdc.gov/flu/index.htm>. We are not requiring health care workers be immunized in this rule. We believe the current LTC requirements provide adequate incentives for LTC facilities to develop immunization protocols for their health care workers.

Comment: One commenter stated that CMS should address the commenter's concern that student nurses are not covered under the OSHA blood borne pathogens requirements for hospitals.

Response: We agree that it is important for health care workers to be immunized in order to protect residents. OSHA seeks to assure the safety and health of America's workers by setting and enforcing standards; providing training, outreach, and education; establishing partnerships; and encouraging continual improvement in workplace safety and health. As indicated above, we require nursing facilities to take steps to prevent staff transmission of disease. These requirements apply to all staff, whether or not they are students.

Payment and Coverage

Comment: One commenter stated that after publishing the final regulation and paying for the program for a year or two, Medicare might decide that the LTC facilities should be responsible for the immunizations and stop paying for them.

Response: In accordance with section 1861(s)(10) of the Social Security Act, Medicare covers both influenza and pneumococcal vaccines. Medicare began covering annual influenza immunizations in 1993 for Medicare beneficiaries. Medicare covers both the costs of the vaccine and its administration. There is no coinsurance or co-payment applied to this benefit, and a beneficiary does not have to meet his or her deductible to receive this benefit. Medicare began covering

pneumococcal polysaccharide vaccinations in 1981. Medicare provides coverage for one pneumococcal polysaccharide vaccine per beneficiary. One vaccine at age 65 generally provides coverage for a lifetime, but for some high risk persons, a booster vaccine is needed. Medicare will cover a booster vaccine for high risk persons if 5 years have passed since the last vaccination. Medicare covers both the costs of the vaccine and its administration. There is no coinsurance or co-payment applied to this benefit, and a beneficiary does not have to meet his or her deductible to receive it. These programs are described in detail on the CMS Web site (<http://www.cms.hhs.gov/preventiveservices/2.asp>). The Medicare reimbursement for influenza and pneumococcal immunizations has never been decreased or denied since it was started; in fact, payment amounts have increased. The 2005 influenza vaccination administration reimbursement rate is \$18 (unweighted average of Medicare "National Flu Biller Administration Codes"). The 2005 Influenza vaccine reimbursement rate is \$10.10 (Medicare rate; 95 percent of Average Wholesale Price (AWP)). Facilities that immunize their residents are not only reimbursed by Medicare but also experience cost savings because there is less illness among their residents.

Comment: A few commenters argued that it is wrong to withhold Medicare payments to LTC facilities that do not provide flu and pneumococcal immunizations to nursing home residents. One commenter stated, "I am frustrated that you would consider linking nursing home payments to vaccinations." However, another commenter praised the proposed rule as being "well thought out" and said that the rule, "importantly, does not penalize the facility if the resident or the resident's legal representative refuses immunization or there are medical contraindications."

Response: Several commenters misunderstood the proposed rule. This rule does not penalize a facility financially if the resident or the resident's representative refuses immunization. In this final rule, we are making it clear that residents must be immunized unless there is a medical contraindication or the resident or resident's legal representative refuses. Therefore, if the LTC facility offers immunization, but the resident refuses, this would not be considered non-compliant.

Comment: One commenter recommended that CMS authorize

Medicare payments to SNFs for the outlier cost of intravenous antibiotics.

Response: The cost of intravenous antibiotics to SNFs is not within the purview of this regulation. SNFs are reimbursed as per the PPS payment rates, which cover all costs of furnishing covered SNF services (routine, ancillary, and capital-related costs).

Comment: One commenter stated that the nursing facilities should have information on billing related to immunizations.

Response: Information and guidance about billing for influenza and pneumococcal vaccinations, including electronic billing, is currently available to all providers at: <http://www.cms.hhs.gov/medlearn/flupdf.pdf>. Alternately, LTC facilities may contact their Medicare Administrative Contractors.

Comment: One commenter stated that CMS should direct Quality Improvement Organizations (QIOs) to increase immunization rates among nursing home residents and staff as a part of the core activities in the QIO Statement of Work with necessary additional funding apportioned for these efforts.

Response: QIOs currently conduct projects focused on improving the health of all Medicare beneficiaries. These projects include, for example, efforts to improve diabetes care and the delivery of mammography and adult immunizations (influenza and pneumococcal). The goals of the adult immunization projects are to increase influenza and pneumococcal immunization rates for Medicare beneficiaries and improve treatment for pneumonia. Descriptions of these projects are available on the Medicare Quality Improvement Center (MedQIC) Web site at (<http://www.medqic.org>).

Comment: One commenter stated that CMS should encourage superior performance on rates of resident and staff immunizations by posting performance information on Nursing Home Compare and including such measures as part of any LTC pay-for-performance.

Response: We appreciate the comment. Incentives for high performance are beyond the purview of this rule. The MDS 3.0 is being modified to include immunizations, and is part of our effort to collect data that can be easily accessed for comparative study. Other efforts may follow including posting of performance information on the Nursing Home Compare Web site.

Comment: One commenter stated that we do not have enough data on the number of LTC residents who have medical contraindications to

immunization or who refuse immunization to determine whether we need to require facilities to offer immunization to all LTC residents. Another commenter protested the burden associated with the rule and recommended that immunization be a voluntary program.

Response: We agree that additional data would be useful. By requiring documentation of these data in residents' medical records, we expect to have the data available for reference in the future. However, as we stated in the preamble of the proposed rule, studies indicate that many LTC facility residents are not being immunized, despite the fact that these services are covered by Medicare. It is clear that voluntary immunization of residents is not adequate to ensure that all residents are being offered immunization.

Comment: One commenter asks for clarification of the qualifications of the person who educates the resident or their representative on immunizations.

Response: We believe it is important to give LTC facilities the flexibility to decide who will provide the education to the residents or their representatives, based on the resources available at the LTC facility. We are not requiring health care workers to be immunized in this rule.

Comment: One commenter expressed concern that time constraints may result in implementation problems for facilities that must have policies and procedures in place by the effective date of the regulation. The commenter also noted that the 15-day comment period was not adequate for individuals and organizations to provide a thorough response, especially for organizations that would like their comments to reflect the opinions of their members.

Response: The rule was expedited and published with a 15-day comment period so that it would be effective for the 2005–2006 flu season. We believe this rule will save lives, and a delay in implementation of the rule would greatly hinder increased immunization of residents in LTC facilities before the onset of this year's influenza season. Therefore, a 60-day comment period was considered contrary to public interest. However, we understand that it may be difficult for LTC facilities to have their policies and procedures in place by the effective date of the rule. We expect facilities to begin implementation of the rule and move their implementation forward as quickly as possible. If surveyed by the State Survey Agency, they should be ready to discuss with the surveyors their process and plans. Since this rule is effective on publication, we expect surveyors will

survey for these requirements with the understanding that facilities need a certain amount of time to fully implement the requirement. Surveyors will take the time factor into consideration as they review facilities for compliance with the CoPs.

Comment: Two commenters asked for clarification regarding what facilities must do between October 1 and March 31. One commenter asked whether influenza vaccination must be offered to a resident who is admitted on March 31, even if the vaccine will not be administered immediately because it is unavailable.

Response: We expect facilities to use common sense in regard to residents admitted toward the end of March when supplies of the vaccine may be limited or unavailable. If the vaccine is unavailable, then the facility will not be able to vaccinate the new resident, and the facility can document this in the resident's record.

Comment: One commenter said, "Let the physicians make the medical decisions. If inappropriate medical decision making then results in a pandemic, only then would a Federal mandate be justified."

Response: The purpose of immunization is to avoid illness or death. The value of immunization is minimal once influenza is widespread.

Comment: One commenter recommended that CDC and CMS work collaboratively to create an electronic health record that would include standard immunization verification information for Medicare beneficiaries.

Response: CMS is in the process of including immunization status of all LTC facility residents in MDS 3.0. Also, on May 28, 2004, DHHS awarded a grant to promote the use of electronic health records to improve the quality of care provided to Americans by supporting a pilot project to provide comprehensive, standardized electronic health record (EHR) software to the health care community. In addition, DHHS has a recently-appointed National Coordinator of Health Information Technology, whose mission includes developing, maintaining, and directing the implementation of a strategic plan to guide the nationwide implementation of interoperable health information technology in both the public and private health care. More information can be found on the DHHS Web site at <http://www.dhhs.gov>.

Comment: One commenter stated that assisted living residents should also be immunized because these high risk individuals fall under the CDC's Advisory Committee on Immunization Practices (ACIP) priority grouping.

Response: We agree; however, CMS does not have the statutory authority, through the Medicare program, to regulate the care provided in assisted living facilities. Generally, assisted living facilities are regulated and monitored by the states in which they are located.

Comment: One commenter requested clarification in the final rule on whether it applies to skilled nursing services provided in hospital swing beds.

Response: This rule is a Condition of Participation for nursing facilities and does not apply to skilled nursing services provided in hospital swing beds. However, there is nothing to prevent hospitals from immunizing this population.

Comment: One commenter said that our statement in the preamble that, "epidemics of influenza have been responsible for an average of approximately 36,000 deaths per year in the United States between 1990 and 1999" is incorrect because fewer than 10 percent of the 36,000 deaths were from the flu. The commenter's conclusion was that since there are not very many deaths from influenza, immunization is not needed.

Response: The commenter does not explain why the commenter thinks the statistic we provided in the preamble to the proposed rule overstates the number of deaths from influenza.

According to "Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP)" (MMWR 29 July 2005;54[RR08]:1–40), "Influenza-related deaths can result from pneumonia and from exacerbations of cardiopulmonary conditions and other chronic diseases. Deaths of older adults account for > 90 percent of deaths attributed to pneumonia and influenza. In one study of influenza epidemics, approximately 19,000 influenza-associated pulmonary and circulatory deaths per influenza season occurred during 1976–1990, compared with approximately 36,000 deaths during 1990–1999. Estimated rates of influenza-associated pulmonary and circulatory deaths/100,000 persons were 0.4–0.6 among persons aged 0–49 years, 7.5 among persons aged 50–64 years, and 98.3 among persons aged > 65 years. In the United States, the number of influenza-associated deaths might be increasing in part because the number of older persons is increasing. In addition, influenza seasons in which influenza A (H3N2) viruses predominate are associated with higher mortality; influenza A (H3N2) viruses predominated in 90 percent of influenza seasons during 1990–1999, compared

with 57 percent of seasons during 1976–1990.

Comment: One commenter stated that a recent study shows no decreased morbidity or mortality from the flu, despite rising rates of vaccination. One commenter specifically cited last year's data as indicating that the flu vaccine is not effective.

Response: As referenced earlier in this preamble, the Simonsen study published in September 2005 found an overall increasing trend in the number of flu-related hospitalizations in the United States each year, despite the fact that the number of immunizations for influenza has increased. In response, the CDC has pointed out that (1) The range of influenza-related illnesses analyzed in the study is broader than in the previous study; (2) certain influenza viruses that predominated in several recent influenza seasons are associated with higher numbers of serious illnesses than other strains; (3) the U.S. population is growing older and more vulnerable to developing severe complications; and (4) during the 1990s influenza viruses have either circulated or been detected for longer periods of time.

It is true that influenza vaccine is not as effective in the elderly as it is in younger individuals. As discussed earlier in this preamble, although influenza vaccine effectiveness varies in the elderly, vaccination is still effective at preventing severe illness, secondary complications, and death. Recommendations made by ACIP in 2004 state that in the elderly population residing in nursing homes, the vaccine can be 50–60 percent effective in preventing hospitalization or pneumonia and 80 percent effective in preventing death, even though the effectiveness in preventing influenza illness often ranges from 30 percent to 40 percent. A study published in *Lancet* in September 2005 found that when used in nursing facilities, influenza vaccines prevented up to 42 percent of deaths from influenza and pneumonia.

Comment: One commenter asked whether Medicare Part B or Part D will pay for the immunizations.

Response: As we stated earlier, immunization is covered under Part B coverage, and Medicare will reimburse one flu vaccination per person per season. This may result in more than one bill per 12-month period across two flu seasons. Further information can be accessed online on the "immunizations toolkits" Web page at (<http://www.medqic.org>).

Comment: One commenter requested that CMS provide policy guidance with respect to immunizing residents who

are receiving end-of-life care. The commenter expressed concern about potential side effects in residents who may have only weeks to live.

Response: We would expect that when a resident is receiving end-of-life care, the resident's attending practitioner would decide whether vaccination should be offered to the resident.

Comment: One commenter stated that we greatly underestimated the burden associated with documentation because documenting immunization in residents records will take more than 5 minutes.

Response: After further consideration of the time required for documentation, we agree with the comment and have increased the estimated amount of time in the burden estimate from 5 minutes to 10 minutes.

Comment: One commenter stated that influenza vaccine does not work in the elderly because of their age.

Response: CDC states that "persons with certain chronic diseases might develop lower post vaccination antibody titers than healthy young adults." It further states that the vaccine can also be effective in preventing secondary complications and reducing the risk for influenza-related hospitalization and death among adults aged >65 years with and without high-risk medical conditions (for example, heart disease and diabetes). Among older persons who do reside in nursing homes, influenza vaccine is most effective in preventing severe illness, secondary complications, and deaths. See <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5408a1.htm>. The CDC also provided the following information in its discussion of the Simonsen study. Observational studies, to date, have generally found that when the "match" between the vaccine and circulating influenza strains is close, the vaccine is 30 percent–70 percent effective in preventing hospitalization for pneumonia and influenza among elderly persons living outside chronic-care facilities (such as nursing homes) and those persons with long-term (chronic) medical conditions. Observational studies have also found that among elderly nursing home residents, the flu shot can be 50 percent–60 percent effective in preventing hospitalization for pneumonia and up to 80 percent effective in preventing death from the flu. See <http://www.amda.com/clinical/immunization/flustudy.htm>.

Comment: One commenter was concerned that by including October 1 in the regulation's text, facilities were being required to begin immunizing residents on that date. The commenter further stated that if the influenza

immunization is given too early in the flu season, the resident's resistance may wane over time. The commenter also stated that facilities are guided by CDC information on how many early flu cases are occurring and that often, the best date to begin immunizing for the flu is November 1.

Response: In choosing the October 1 through March 31 dates, we are following the guidelines that CDC has provided for the beginning and end of the flu season. Although flu season can begin as early as October, facilities should follow CDC guidelines for each flu season to determine the most efficacious time to begin immunizing their residents. The CDC states in "When to Get Vaccinated" that October or November is the best time to get vaccinated, but getting vaccinated even later (before March 31) can still be beneficial.

Comment: One commenter expressed concern regarding possible consequences that would result from a resident refusing immunization.

Response: The rule clearly gives the right to the residents and their representatives to refuse immunization if they choose. Therefore, there would be no adverse effect or consequence because of the refusal. The existing CoP at 42 CFR 483.10 on resident rights, also provides freedom of choice to the resident.

Comment: One commenter objected to the estimate of \$5 million per statistical life saved and stated "While all life is sacred, placing \$5 million per life saved on someone likely to die in a few weeks or months is exaggerated and unjustified. The commenter further stated that the savings are grossly inflated through use of this estimate."

Response: Five million dollars per statistical life saved is a figure commonly used by Federal agencies. Although the age of the affected population has been identified as an important factor in the theoretical literature on the value of a statistical life (VSL), the empirical evidence on age and VSL is mixed. In light of the continuing questions over the effect of age on VSL estimates, OMB Circular A-4 recommends that agencies not use an age-adjustment factor in an analysis using VSL estimates. We could have used an alternative measure, such as statistical years of lives saved, but that would not have changed the overall conclusion that the benefits of the rule are substantial. In fact, the savings to Medicare alone are sufficient to make the rulemaking cost-beneficial, therefore the choice of how to value the lives saved due to this rulemaking is not decision critical.

Comment: One commenter stated that CMS, at the very least, should describe within the rule a standardized format for obtaining required documentation. This will protect the facility from liability and provide a guide for surveyors.

Response: The final rule provides flexibility to the facilities on how to document the information. This flexibility gives facilities the opportunity to choose the process and format that works best for them.

Comment: One commenter expressed concern that by placing the requirements of the rule in § 483.25, rather than § 483.65, the facility could be subject to termination of the nurse aide training program if documentation deficiencies are widespread and the facility is found to be providing substandard care.

Response: We believe this new requirement is appropriately placed under the "Quality of Care" CoP. It is more than just a documentation requirement. The extent of the deficient practices found in meeting this requirement during a survey will determine the type of enforcement warranted.

Comment: One commenter wanted us to define a "legal" representative.

Response: As they implement the requirements of the rule, we expect that facilities will be guided by the laws that pertain to the definition of "legal representative" of the states in which the facilities are located. Due to the variations in state law, we are not defining the term "legal representative."

Comment: One commenter asked for clarification of the "exception" under (2)(iv), specifically the requirements for the assessment.

Response: We expect that the residents practitioner would decide on the degree of assessment necessary to determine if a second immunization is warranted in order to provide protection for the resident.

IV. Provisions of the Final Regulations

For the most part, this final rule incorporates the provisions of the proposed rule. The provisions of this final rule that differ from the proposed rule are as follows:

1. Based on comments, LTC facilities must provide education to residents or the resident's legal representative concerning influenza and pneumococcal immunization prior to immunization. Further we modified the regulation to include not just the benefits but also the potential side effects of influenza and pneumococcal immunization when education is provided to the resident or resident's legal representative.

2. We have listed some of the minimum documentation requirements and still provide the facilities the flexibility to document any additional information they believe is relevant. (See 483.25(n)(2)(iv).)

V. Waiver of the 60-Day Delay in Effective Date

We ordinarily provide a 30-day delay in the effective date of the provisions of a rule in accordance with the Administrative Procedure Act (APA) (5 U.S.C. 553(d)), which requires a 30-day delayed effective date. The Congressional Review Act (5 U.S.C. 801(a)(3)), requires a 60-day delayed effective date for major rules. As stated in our regulatory impact analysis below, we believe this is a major rule. However, we can waive the delay in effective date if the Secretary finds, for good cause, that such delay is impracticable, unnecessary, or contrary to public interest, and incorporates a statement of the finding and the reasons in the rule issued. 5 U.S.C. 553(d)(3); 5 U.S.C. 808(2).

The Secretary finds that good cause exists to implement the requirements related to the LTC facilities offering each resident immunization against influenza annually, as well as lifetime immunization against pneumococcal disease immediately upon publication in the **Federal Register**. In accordance with section 1871(b)(2)(C) of the Act, we have waived the delay in the effective date for this final rule from 60-day delay to an immediate effective date to allow for implementation of the requirements in time for the 2005–2006 flu season. It is our view that a 60-day delay in effective date on this final rule will be extremely detrimental to the health of nursing home residents, as epidemics of influenza typically occur during the winter months and are responsible for an average of approximately 20,000 to 40,000 deaths per year in the United States. Influenza viruses also can cause pandemics, during which rates of illness and death from influenza-related complications can increase dramatically. Rates of infection are highest among children, but rates of serious illness and death are highest among persons 65 and older and persons of any age who have medical conditions that place them at increased risk for complications from influenza and pneumonia. Vaccines are the most effective means to protect against many complications related to influenza and pneumonia. The ACIP recommendations for 2004 to 2005, to decrease the risk of influenza, state that the optimal time for influenza vaccinations is October through

November. If expedited and published with an immediate effective date, a delay can be prevented and the rule can be effective in the 2005–2006 flu season, with the potential of saving many lives and preventing illness.

One of our goals of publishing this rule is to increase immunization rates in nursing homes to 90 percent, which is the Healthy People 2010 goal. This will enable about half a million elderly individuals who are not currently immunized to be immunized. The CMS/CDC standing orders project in 2003 found that in nursing home residents, influenza vaccine is associated with a 31–33 percent reduction in mortality, and a 38–45 percent reduction in all-cause hospitalizations. Similarly, pneumococcal vaccination is associated with a 21–22 percent reduction in mortality, and a 27–28 percent reduction in all-cause hospitalization. We recognize that these associations are not necessarily causal because the data are cross-sectional with no correction for confounding variables. However, the findings are consistent with findings regarding immunization in the general population. Therefore, it is imperative that this final rule is published with an immediate effective date so that the requirements can be implemented in time for the 2005–2006 flu season. Even though pneumococcal vaccines can be administered throughout the year, the percentage of patients and residents immunized remains low. Therefore, this final rule would be a vehicle to improve immunization rates and would be consistent with the Healthy People 2010 objective.

We believe that a delay in implementation of this rule would greatly hinder increased immunization of residents in LTC facilities before the onset of this year's influenza season. We conclude that, in this instance, a 60-day delay in effective date is unnecessary and contrary to public interest. We find on this basis, that there is good cause for waiving the 60-day delay in effective date under section 1871(b)(2)(C) of the Act.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-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 are soliciting public comment on the following information collection requirements contained in this document.

This rule does require facilities to develop specific documentation. As a facility develops and implements immunization protocols or procedures, we expect that obtaining previous immunization history on each resident, when possible, would be a part of the process. Additionally, we expect the facility would document in the resident's medical record information concerning immunization history, contraindications etc. as a part of the process of immunizing residents.

The burden associated with these requirements in the first year, would be approximately 10 hours of a registered nurse's time per facility that is 161,390 hours for the first year (10 hours × 16,139 facilities). In subsequent years, we estimate that the burden associated approximately 10 minutes of the registered nurse's time, which would be 16,139,000 minutes = 268,983 hours per year (10 minutes per resident × 100 residents per facility × 16,139 facilities). Based on the latest data in an Online Survey Certification and Reporting System (OSCAR), there are 16,139 facilities.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following: Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn: Jim Wickliffe, CMS–3198–F, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Christopher Martin, CMS Desk Officer, CMS–3198–F, Christopher_Martin@omb.eop.gov. Fax (202) 395–6974.

VII. Regulatory Impact

A. Overall Impact

We have examined the impacts of this rulemaking as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, Executive Order 13132 (August 4, 1999, Federalism), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to issue regulations only after consideration of 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). A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects (\$100 million or more in any 1 year). This final rule is an economically “significant regulatory action” as defined by section 3(f) of Executive Order 12866, and a “major rule” as defined in the Congressional Review Act. We have reached this conclusion because of the substantial life-saving effects of the rule and its anticipated reduction in the medical costs associated with influenza and pneumonia. We believe that there are no significant costs associated with this final rule. It will not impose any mandates on State, local, or tribal governments, or the private sector that will result in an expenditure of \$100 million in any given year. Since most program participants comply with the statutory and regulatory requirements making unnecessary the imposition of termination from Medicare, Medicaid and, where applicable, other Federal health care programs, and since Medicare generally pays the cost of the vaccines that are the subject of this rule we do not anticipate more than a minimal economic impact on nursing facilities as a result of this proposed rule. There is a cost to the Medicare program for the vaccines to the extent that they are provided to Medicare beneficiaries, as discussed below.

This final rule will have a life-saving effect. We have developed estimates of these life-saving effects, along with estimated changes in medical care costs, and present these estimates and the assumptions on which they are based in the discussion and tables that follows.

Influenza

Assumptions (Benefit): There are approximately 2 million residents in LTC facilities. Sixty-five percent had documentation stating they received influenza immunization per the 1999 National Nursing Home Survey, National Center for Health Statistics, CDC. An October 2000 article in the Journal of American Geriatric Society "Influenza outbreak detection and control measures in nursing homes in the United States (Zadeh MM, Buxton Bridges C, Thompson WW, Arden NH, Fukuda K.)" indicated that 83 percent of LTC residents in the study received immunizations. The midpoint between the two reports is 74 percent. The projected immunization rate after regulation implementation is 90 percent.

The 2005 influenza vaccination administration reimbursement rate is

\$18 (unweighted average of Medicare "National Flu Biller Administration Codes"). The 2005 Influenza vaccine reimbursement rate is \$10.10 (Medicare rate; 95 percent of Average Wholesale Price (AWP)). There is a wide variation in the influenza rate year to year, due to the prevalent strains of influenza virus each influenza season and the degree to which the vaccine matches prevalent strains as well as other factors. Effectiveness of influenza vaccine for preventing influenza illness is 30–40 percent according to ACIP (Harper SA, Fukuda K, Uyeki TM, Cox NJ, Bridges CB; Prevention and control of influenza: recommendations of the ACIP. MMWR Recomm Rep. 2004 May 28; 53(RR-6):1–40).

As stated above, the rate of hospitalization for the LTC population among those ill with influenza is 25 percent (Arden NH, et al.). The

influenza vaccine is 50–60 percent effective in preventing hospitalization due to influenza in the LTC population (ACIP, May 2004).

According to (Arden NH, et al.) the case-fatality for influenza disease in the LTC population is 10 percent of the number of residents who become ill with influenza. The influenza vaccine is 80 percent effective in preventing death in LTC residents with influenza illness (ACIP, May 2004). The average Medicare cost per hospital discharge for influenza is \$8,500 per the Office of the Actuary, CMS (including medical education, disproportionate share and other pass through). The data on the influenza related hospitalization of SNF residents is not available. SNF residents are short term stay therefore we do not think those numbers are sufficiently large to have a great impact on the overall Medicare costs.

TABLE 1.—ESTIMATED FEDERAL BENEFITS DUE TO INCREASED RATE OF INFLUENZA IMMUNIZATIONS

LTC residents	Current	Projected	Difference
Percent who receive influenza immunization	74%	90%	16%
Number who receive influenza immunization	1,480,000	1,800,000	320,000
Number ill with influenza	133,380	123,300	(10,080)
Number hospitalized due to influenza	20,358	15,030	(5,328)
Number who die from influenza complications	7,344	5,040	(2,304)
Direct Medicare cost of inpatient hospital treatment	\$173,043,000	\$127,755,000	(\$45,288,000)

Assumptions (Cost): Influenza vaccine must be administered annually; however, virtually all influenza vaccinations administered in LTC facilities are covered under the Medicare Part B program. The cost to Medicare for provision of the influenza vaccinations is equal to the cost of the vaccines plus administration costs. In addition to these direct Medicare costs,

an indirect Federal cost will be incurred from reduced savings in the Medicaid program. For every hospitalization of a LTC facility resident, Medicaid saves \$1,000 for nursing home care not provided while the resident is in the hospital. The weighted average of the federal contribution to Medicaid is 57 percent (Office of the Actuary, CMS), and Medicaid is a primary source of

payment for 40 to 59 percent of LTC facility residents (1999 National Nursing Home Survey) and with a midpoint of 50 percent. The total federal cost related to the increased influenza immunizations is the total of the direct Medicare costs combined with the lost savings to Medicaid.

TABLE 2.—ESTIMATED FEDERAL IMPACT OF INCREASED INFLUENZA IMMUNIZATION ON MEDICARE & MEDICAID

	Current (\$)	Projected (\$)	Difference
Total Medicare reimbursement for cost of influenza vaccine and administration (320,000 × \$28.10)	41,588,000	50,580,000	\$8,992,000
Federal share of Medicaid LTC facility savings due to resident hospital stays*	(5,802,030)	(4,283,550)	1,518,480
Total Federal Costs	35,785,970	46,296,450	10,510,480

* (Number of residents hospitalized) × (\$1000 cost for NH facility per hospitalization) × (57% Federal portion of Medicaid payments) × (50% portion of all NH patients paid by Medicaid).

TABLE 3.—NET FEDERAL SAVINGS DUE TO INCREASED INFLUENZA IMMUNIZATION

Estimated Federal Savings (from Table 1)	(\$45,288,000)
Estimated Federal Costs (from Table 2)	\$10,510,480
Total Net Federal Savings	(\$34,777,520)
Lives saved per year	2,304

* Negative numbers reflect savings.

We have used an average value of a statistical life of \$5 million to monetize the decreased mortality benefits of the rule, as we have in other rulemakings. This value is in the middle of the range of \$1–\$10 million per statistical life saved recommended by OMB Circular A–4. The population affected by this rule has different demographic and other characteristics from the populations that were addressed in other CMS rulemakings. However, due to the lack of data on this specific population, we are assuming a value of \$5 million for the average value of a statistical life for this rule. In addition, although the age of the affected population has been identified as an important factor in the theoretical literature, the empirical evidence on age and VSL is mixed. In light of the continuing questions over the effect of age on VSL estimates, OMB Circular A–4 recommends that agencies not use an age-adjustment factor in an analysis using VSL estimates.

Therefore, since we estimate 2,304 lives will be saved by the influenza vaccination, we estimate the value saved from saving these lives as \$11.5 billion.

As previously indicated in response to a comment, this estimate would be

lower if we used an alternate measure such as statistical years lives saved. In addition, VSL is an inherently uncertain measure of value. By any reasonable measure of the value of these medical improvements, however, the benefits would, nonetheless, be very substantial.

Invasive Pneumococcal Disease

Assumptions (Benefit): There are approximately 2 million residents in LTC facilities. The projected immunization rate after regulation implementation is 90 percent. The LTC resident vaccination rate is estimated between 39 percent (1999 National Nursing Home Survey (NNHS)) and 56 percent (community rate, 2003 National Health Interview Survey). Virtually all residents with invasive disease are hospitalized. The rate of pneumococcal invasive disease in unvaccinated persons aged greater than or equal to 65 equals 52–85/100 000, (ACIP, 1997). The case fatality ratio of invasive pneumococcal disease in persons aged greater than or equal to 65 (despite appropriate medical treatment) is 30–40 percent. The average cost per hospital discharge for invasive pneumococcal disease is \$8500 (including medical education, disproportionate share and other pass through) (Office of the

Actuary, CMS). According to CDC recommendations, usually one dose of the pneumococcal polysaccharide vaccine (PPV) is all that a person needs in a lifetime. However, in some situations a second dose is recommended for people 65 and older. Therefore, expense related to this rule is projected to cost more at the beginning period of implementation.

The 45 percent documented immunization rate in the table below represents data obtained in the year 1999, and since then the rate may have increased. Implementing the influenza immunization process is more challenging than implementing the similar PPV immunization process. Pneumococcal immunizations can be given all through the year without time constraints and the vaccine supplies have not been an issue. We anticipate that implementation of this rule would result in increase in immunization rate and documentation of the related data for future comparison. The table below is relating the years 1–5 to the current data.

Invasive Pneumococcal Disease

Assumptions (Benefit):

TABLE 4.—ESTIMATED FEDERAL BENEFITS DUE TO INCREASED RATE OF PNEUMOCOCCAL IMMUNIZATIONS

LTC residents	Current year	Projected				
		Year 1	Year 2	Year 3	Year 4	Year 5
Percent who receive pneumococcal immunization	45%	70%	75%	80%	85%	90%
Number who receive pneumococcal immunization per year		500,000	100,000	100,000	100,000	100,000
Cumulative number immunized (since inception of Medicare pneumococcal immunization benefits)	900,000	1,400,000	1,500,000	1,600,000	1,700,000	1,800,000
Number who develop invasive pneumococcal disease	970	742	697	651	606	560
Deaths from invasive pneumococcal disease (or complications related to the disease)						
Benchmark—Number of deaths without increased immunizations	340	340	340	340	340	340
Number of deaths following implementation of immunization regulation		260	244	228	212	196
Number of lives saved due to pneumococcal immunization		80	96	112	128	144
Direct Federal costs for treatment of invasive pneumococcal disease						
Benchmark—costs without increased immunizations	\$8,246,190	\$8,246,190	\$8,246,190	\$8,246,190	\$8,246,190	\$8,246,190
Costs following implementation of immunization regulation		\$6,310,740	\$5,923,650	\$5,536,650	\$5,149,470	\$4,762,380
Savings following implementation of increased pneumococcal immunizations		(\$1,935,450)	(\$2,322,540)	(\$2,709,540)	(\$3,096,720)	(\$3,483,810)

Assumptions (Cost): The 2005 pneumococcal vaccination administration reimbursement rate is

\$18 (unweighted average of Medicare “National Flu Biller Administration Codes”) and the pneumococcal vaccine

reimbursement rate is \$23.28 (Medicare rate; 95 percent of AWP). The pneumococcal vaccine is generally

administered once per beneficiary lifetime. Therefore this is not a recurring cost, but would cost more up front to give lifetime immunity to residents (for the cost estimate, we assumed 500,000 people would receive the vaccine in the first year and 100,000 people each would receive the vaccine in years two through five). The reason we assume the higher number the first year is because we expect all the eligible residents in the facilities in the first year would

receive the pneumococcal vaccine. In the following years only the new residents who are eligible would need the immunization. Virtually all pneumococcal immunizations administered in LTC facilities are covered under the Medicare Part B program. For every hospitalization concerning Medicaid beneficiaries, Medicaid saves \$1000 for nursing home care not provided while the resident is in the hospital. The weighted average of

the Federal contribution to Medicaid is 57 percent (Office of the Actuary, CMS). Medicaid is a primary source of payment for 40 to 59 percent in LTC (1999 National Nursing Home Survey) and the mid point is 50 percent. The total Federal cost related to the increased pneumococcal immunizations is the total of the direct Medicare reimbursement costs combined with the lost savings to Medicaid.

TABLE 5.—FEDERAL IMPACT OF INCREASED PNEUMOCOCCAL IMMUNIZATION ON MEDICARE AND MEDICAID

	Current year (\$)	Projected (\$)				
		Year 1	Year 2	Year 3	Year 4	Year 5
Medicare reimbursement for cost of pneumococcal vaccine and administration						
Annual Medicare cost following increased pneumococcal immunization*.		20,640,000	4,128,000	4,128,000	4,128,000	4,128,000
Cumulative Medicare cost (since inception of Medicare pneumococcal immunization benefits).	37,152,000	57,792,000	61,920,000	66,048,000	70,176,000	74,304,000
Federal share of Medicaid LTC facility savings due to resident hospital stays						
Federal savings per year without increased immunizations**.	(276,490)	(276,490)	(276,490)	(276,490)	(276,490)	(276,490)
Federal savings per year following increased pneumococcal immunization**.		(211,595)	(198,617)	(185,638)	(172,659)	(159,680)
Lost Federal savings due to increased pneumococcal immunization.		64,895	77,874	90,852	103,831	116,810
Total Federal Costs (annual Medicare costs + lost Federal savings).	Not Available	20,704,895	4,205,874	4,218,852	4,231,831	4,244,810

* Year 1 (500,000 × \$41.28); Years 2–5 (100,000 × \$41.28).

** (# of residents hospitalized) × (\$1000 cost for NH facility per hospitalization) × (57% Federal portion of Medicaid payments) × (50% portion of all NH patients paid by Medicaid).

TABLE 6.—NET FEDERAL COSTS DUE TO INCREASED PNEUMOCOCCAL IMMUNIZATION

Year 1:	
Estimated Federal Savings (from Table 4)	(\$1,935,450)
Estimated Federal Costs (from Table 5)	\$20,704,895
Total Net Federal Cost in Year 1	\$18,769,445
Years 2–5: Estimated Federal savings (from table 4) + Estimated Federal costs (from table 5):	
Total Net Federal Cost in Year 2 (\$2,322,540) + 4,205,874	\$1,883,334
Total Net Federal Cost in Year 3 (\$2,709,540) + 4,218,852	\$1,509,312
Total Net Federal Cost in Year 4 (\$3,096,720) + 4,231,831	\$1,135,111
Total Net Federal Cost in Year 5 (\$3,483,810) + 4,244,810	\$761,000
Total Net Federal Cost Years 1–5	\$24,058,202
Lives saved Years 1–5	560

Using the same \$5 million per life value of a statistical life as before and since we estimate 560 lives will be saved by the pneumococcal vaccination, we estimate the value saved from saving these lives as \$2.8 billion.

For the purpose of this analysis we have considered the protective effects of influenza and pneumococcal immunization individually. However, the combined effect of both immunizations is additive in preventing

hospitalization and deaths. The July 30, 1999 article in the journal "Vaccine" titled "The additive benefits of pneumococcal vaccinations during influenza seasons among elderly persons with chronic lung disease" reports that both vaccinations together demonstrated additive benefit as there was a 65 percent reduction in hospitalization for pneumonia and 81 percent reduction in death versus the situation when neither had been

received. Also excluded in this analysis is the increased protection against influenza infection afforded by the "herd" effect after 80 to 90 percent of residents are immunized against influenza. The 2003, CMS/CDC standing orders project report states that a facility-level influenza vaccination of 80 percent and more of residents may be independently associated with reduced patient hospitalization and death. Further, the cost-saving effects of this

rule, and the costs of the vaccine doses themselves, are respectively benefits and costs to the taxpayer. Since Medicare pays virtually all medical, hospital, and (starting in 2006) drug costs for this population, the expected

savings from reduced hospitalizations would largely accrue to the Federal budget.

In order to comply with this rule, facilities will develop the necessary policies and procedures which will be

followed by staff as a standard practice. We estimate the time and cost related to this process in the following tables:

POLICY AND PROCEDURE DEVELOPMENT RELATED TO THE IMMUNIZATION RULE

[This is only a one time expense for the facilities]

Number of LTC facilities	Hours spent per facility	Total burden hours	Total cost
16,139	10 hours first year only	161,390 hours only first year	161,390 hours × \$23.70* = \$3,824,943.

* \$23.70 is the average salary of a registered nurse as per U.S. Department of Labor (<http://www.bls.gov/oes/current/oes291111.htm#nat>).

This rule proposes that the resident's immunization status be documented in

the resident's medical record therefore, the following table presents the

estimated time and cost related to the implementation of this process.

DOCUMENTATION TIME OF IMMUNIZATION

[These expenses are annual]

Number of LTC facilities	Hours spent per resident per facility	Total burden hours	Total cost
16,139	16,139 × 100** residents × 10 minutes = 16,139,000 minutes = 268,983 hours.	268,983	268,982 hours × \$23.70* = \$6,374,897.

* \$23.70 is the average salary of a registered nurse as per U.S. Department of Labor (<http://www.bls.gov/oes/current/oes291111.htm#nat>).

** 100 is the average number of residents in each facility.

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 will have a significant economic impact on a substantial number of small entities and, if so, 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 small businesses, nonprofit organizations, and small government jurisdictions. Most nursing facilities are small entities, either by nonprofit status or by having revenues of \$11.5 million or less annually (the applicable size standard of the Small Business Administration). Individuals and States are not included in the definition of a small entity, and other medical care providers are not affected by this final rule except indirectly, through reduced utilization of care by individuals who do not, but would otherwise, require hospitalization. For the reasons explained in this analysis, we have concluded that this final rule will not have significant impact on a substantial number of small entities.

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 section 604 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 final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars. This final rule will impose no mandates on State, local, or tribal governments. As indicated elsewhere in this analysis, costs mandated on nursing facilities, are minimal, and do not remotely approach this threshold.

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 final rule will not significantly affect the rights, roles, or responsibilities of the States. This final rule will not impose substantial direct requirement costs on State or local governments, preempt State law, or otherwise implicate federalism.

B. Anticipated Effects

1. *Effects on LTC facilities.* Based on the various studies and reports referenced earlier in the preamble, we expect that LTC facilities will benefit from the implementation of this final rule. The various studies discussed are evidence that prevention of influenza and pneumonia will lower the level of acuity, staff time and other expenses resulting in cost reductions.

2. *Effects on beneficiaries.* The influenza vaccine is 50–60 percent effective in preventing hospitalization due to influenza in the LTC population and increased immunizations are expected to improve health overall for the age group of 65 years and older. As estimated above 2,304 lives may be saved annually when residents receive influenza immunizations.

According to CDC's Active Bacterial Core Surveillance for pneumococcal disease, approximately 5,700 deaths from invasive pneumococcal disease

(bacteremia and meningitis) are estimated to have occurred in the United States in 2002. The October 1997 *Journal of the American Medical Association* (JAMA) article "Cost-Effectiveness of Vaccination Against Pneumococcal Bacteremia Among Elderly People" indicated that vaccination of elderly people against pneumococcal bacteremia is one of the few interventions that have been found to both improve health and save medical costs.

3. *Effects on the Medicare and Medicaid Programs.* The report from the January 2000, CMS's Adult Immunization Project, indicates that "despite the fact that influenza and pneumococcal vaccines are clinically effective, cost-effective, and are Medicare Part B covered benefits, they remain underutilized." Increased immunizations are expected to reduce the medical expenses and improve health overall for the age group of 65 years and older as reported in the Oct, 1997 JAMA article referenced earlier. As stated above, the rate of hospitalization for the LTC population among those ill with influenza is 25 percent (Arden NH, et. al.). The average cost per hospital discharge for influenza is \$8,500 per the Office of the Actuary, CMS. The influenza vaccine is 80 percent effective in preventing death in the LTC population (ACIP, May 2004). As estimated above the net saving will be \$34,777,520 and 2,304 lives saved when residents receive influenza immunizations. The net cost related to pneumococcal immunizations is estimated to be \$18,821,360 the first year of implementation and \$3,753,887 in the following 2 to 5 years and 143 lives saved.

C. Alternatives Considered

We considered other alternatives regarding immunizing residents.

1. One alternative would be to keep the present rules, as they are written. The current regulations, however, have thus far not been effective at assisting us in increasing the rate of immunization of institutionalized residents to 90 percent. 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, at-risk individuals are not receiving influenza and pneumococcal vaccines. Section 4107 of the Balanced Budget Act of 1997 extended the influenza and pneumococcal immunization 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 and pneumococcal immunizations was increased under this legislation, rates of immunization did not improve as anticipated.

2. Another alternative would be to educate providers on the value of influenza and pneumococcal vaccines without rule making. However, as discussed in studies cited earlier in this rule, this has not been effective in improving immunization rates.

D. Conclusion

Increasing the utilization of cost-effective preventive services is the goal of both CMS and CDC, and this final rule will facilitate the delivery of appropriate vaccinations in a timely manner, increase the levels of vaccination rate, and decrease the morbidity and mortality rate of influenza and pneumococcal diseases. As a result, the economic effects of the rule are substantial and overwhelmingly beneficial. In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this final rule.

List of Subjects in 42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, and Safety.

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

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 1. The authority citation for part 483 continues to read as follows:

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

Subpart B—Requirements for Long Term Care Facilities

■ 2. Section 483.25 is amended by adding paragraph (n) to read as follows:

§ 483.25 Quality of care.

* * * * *

(n) *Influenza and pneumococcal immunizations*—(1) *Influenza.* The facility must develop policies and procedures that ensure that—

(i) Before offering the influenza immunization, each resident or the resident's legal representative receives education regarding the benefits and

potential side effects of the immunization;

(ii) Each resident is offered an influenza immunization October 1 through March 31 annually, unless the immunization is medically contraindicated or the resident has already been immunized during this time period;

(iii) The resident or the resident's legal representative has the opportunity to refuse immunization; and

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

(A) That the resident or resident's legal representative was provided education regarding the benefits and potential side effects of influenza immunization; and

(B) That the resident either received the influenza immunization or did not receive the influenza immunization due to medical contraindications or refusal.

(2) *Pneumococcal disease.* The facility must develop policies and procedures that ensure that—

(i) Before offering the pneumococcal immunization, each resident or the resident's legal representative receives education regarding the benefits and potential side effects of the immunization;

(ii) Each resident is offered an pneumococcal immunization, unless the immunization is medically contraindicated or the resident has already been immunized;

(iii) The resident or the resident's legal representative has the opportunity to refuse immunization; and

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

(A) That the resident or resident's legal representative was provided education regarding the benefits and potential side effects of pneumococcal immunization; and

(B) That the resident either received the pneumococcal immunization or did not receive the pneumococcal immunization due to medical contraindication or refusal.

(v) *Exception.* As an alternative, based on an assessment and practitioner recommendation, a second pneumococcal immunization may be given after 5 years following the first pneumococcal immunization, unless medically contraindicated or the resident or the resident's legal representative refuses the second immunization.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital

Insurance; and Program No. 93.774,
Medicare—Supplementary Medical
Insurance Program)

Dated: September 23, 2005.

Mark B. McClellan,

*Administrator, Centers for Medicare &
Medicaid Services.*

Approved: September 27, 2005.

Michael O. Leavitt,

Secretary.

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