requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this proposed rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This proposed rule pertaining to the amendments to the Maryland's AIM coatings rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: August 5, 2005.

Donald S. Welsh,

Regional Administrator, Region III.

[FR Doc. 05–16111 Filed 8–12–05; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 483

[CMS–3198–P]

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: Proposed rule.

SUMMARY: The goal of this proposed 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 would be required to ensure that each resident receives an annual immunization against influenza and receives the pneumococcal immunization 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 proposed 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: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 30, 2005.

ADDRESSES: In commenting, please refer to file code CMS–3198–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/regulations/ecomments.* (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3198–P, P.O. Box 8010, Baltimore, MD 21244–8010.

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

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3198–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

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

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Anita Panicker, (410) 786–5646. Jeannie Miller, (410) 786–3164. Rachael Weinstein, (410) 786–6775.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–3198–P and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. CMS posts all electronic comments received before the close of the comment period on its public Web site as soon as possible after they have been received. Hard copy comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

(If you choose to comment on issues in this section, please include the caption ''BACKGROUND'' at the beginning of your comments.)

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. The ACIP reported in 2002 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. As the vast majority of the residents in nursing homes are 65 years and older, or if younger, probably have one or more chronic medical conditions for which the vaccine is indicated, one would expect that nearly all residents are candidates for pneumococcal vaccination. Therefore, it is vital to increase immunization rates to reduce and eliminate vaccine-preventable causes of morbidity and mortality.

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 a memorandum of understanding (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 in those settings designated as appropriate by the ACIP.

A March 24, 2000 ACIP report recommended the use of standing orders programs in both outpatient and inpatient settings to increase the number of individuals who receive the influenza vaccine (*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 now can 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 we do not have data on the specific immunization rates of nursing facility residents since the publication of this rule. 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. These rates demonstrate that we need to implement strategies to help us achieve the goal set by the Department of Health and Human Services (DHHS) Healthy People 2010, which set a target rate of 90 percent for influenza and pneumococcal vaccination for adults aged 65 years and older. 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 at the Morbidity and Mortality Weekly Report (MMWR) website 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 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,'' states 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*).

The Director of Health Care-Public Health Issues for the General Accountability Office (GAO) testified before the United States Senate Special Committee on Aging, on September 28, concerning a 2004 GAO study titled, ''Infectious Disease Preparedness: Federal Challenges in Responding to Influenza Outbreaks'' (*http://www.gao.gov/new.items/d041100t.pdf*). She 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 state 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.

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 elderly (*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. CDC and National Institute of Health (NIH) jointly, in a February 15, 2005, press release (*http://www.cdc.gov/flu/pdf/statementeldmortality.pdf*) concluded that 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, *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, 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 sharp contrast to 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 studies and published research in order to develop the best recommendations for protecting all Americans from influenza. The Simonsen, *et al.*, study is a reminder that there is room for improvement in how we protect the elderly from influenza, and CDC and NIH encourage research that strengthens our ability to do so.

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 deaths from influenza. In the joint press release referenced above, the CDC and National Institute 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'' states 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 life time. 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, multiplemyeloma, 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. In some cases, this may require that they educate residents about the advantages of being vaccinated so that the residents will understand the risks of pneumococcal infections and will be willing to receive the vaccine. 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 state that pneumococcal vaccination has not been causally associated with death among vaccine recipients. Additional information about precautions and contraindications can be attained from CDC and the vaccine manufacturer's package insert should also be reviewed. (*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 states that in 1999, because of concerns about pneumococcal antimicrobial resistance and underuse 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*) states 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 agenda. ''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'' stated 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 un-witnessed 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 of American Family Physician, October 15, 2004, ''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 caused by complications from various infectious diseases, and, as many family members and health care workers know, they can prevent infection of 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 would facilitate the delivery of appropriate vaccinations to residents in LTC facilities in a timely manner and increase vaccination rates, and thereby decrease the morbidity and mortality

rate of influenza and pneumococcal diseases. 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 a 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 would significantly 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 states ''Vaccination of the 23 million elderly people unvaccinated in 1993 would have gained about 78,000 years of healthy life and saved $194 million.''

Pneumococcal vaccination saves costs in the prevention of bacteremia alone and is greatly underused among the elderly population, on both health and economic grounds. These results support recent recommendations of the ACIP and public and private efforts under way to improve 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 who 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 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. Other groups deemed a priority were nursing homes residents. We understand that providers of LTC services may be concerned about how they would meet the requirements of this regulation should an influenza vaccine shortage occur in the future. In the case of a true vaccine shortage as declared by CDC, CMS could exercise its enforcement discretion by instructing the State Survey Agencies (SSAs) not to cite facilities as out-of-compliance with this requirement if they were unable to obtain vaccine for their residents.

II. Provisions of the Proposed Rule

On May 28, 2004, the ACIP recommendations on ''Prevention and Control of Influenza'' (*http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5306a1.htm*), 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; use of reminder/recall systems; and efforts to remove administrative and financial barriers that prevent persons from receiving the vaccines, including use of standing orders programs. We propose to add § 483.25 (n), that would require LTC facilities to offer each resident between, October 1 through March 31, immunization against influenza annually, as well as lifetime immunization against pneumococcal disease. LTC facilities would be required to ensure that each resident receives an annual immunization against influenza and receives the pneumococcal immunization unless medically contraindicated, based on an assessment, or unless the resident or the resident's legal representative refuses consent. As an alternative, a second pneumococcal shot may be given 5 years after the first pneumococcal immunization if the vaccine was administered prior to age 65, and only according to a practitioner recommendation.

We are not proposing to require the development of protocols nor specific documentation. However, 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, this rule proposes that the resident's immunization status be documented in the resident's medical record including but not limited to the information that the resident received influenza or/and *pneumococcal immunization*, or immunization was medically contraindicated, or immunization was refused. If the immunization was refused, documention must include that the resident or the resident's legal representative received appropriate education and consultation regarding the benefits of influenza and *pneumococcal* immunization. Updating and maintaining resident medical records related to immunization was identified as an issue by the CDC. The National Nursing Home Survey (NNHS), conducted in 1995 by the CDC, National Center for Health Statistics, indicated that a large number of nursing facilities did not maintain complete, easily-accessible information on the vaccination status of their residents. Nearly 21 percent of the nursing home residents did not have documentation regarding influenza vaccination, and 43 percent did not have documentation regarding pneumococcal vaccination. Thus, it was difficult to reliably estimate levels of influenza and pneumococcal vaccine use among nursing home residents in 1995. The 1995 NNHS also indicated that facilities with an organized immunization program had higher immunization rates than those without a program. To encourage the development of organized immunization programs in long-term care facilities, CDC created a ''how to'' manual. The manual outlines general recommendations for establishing immunization programs that should integrate seamlessly into the facility's overall policies and procedures for quality care. The manual is available on line at *http://www.cdc.gov/nip/publications/long-term-care.pdf.*

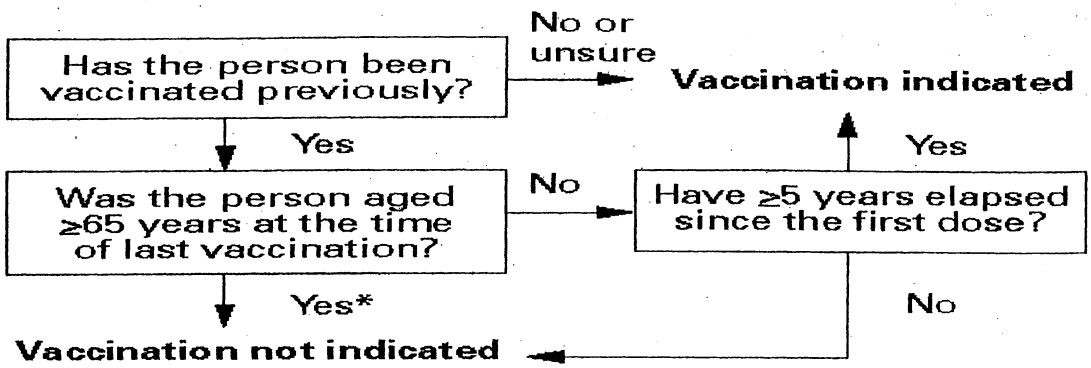
The March 18, 2005 CDC manual titled ''Prevention and Control of

Vaccine-Preventable Diseases in Long-Term Care Facilities,'' Section IV, focuses on the ACIP recommendation related to ''staff immunization to reduce staff illnesses during the influenza season to reduce the spread of influenza from workers to residents'' (*http://www.cdc.gov/nip/publications/long-term-care.pdf*). We acknowledge the importance of staff immunization. In a similar vein, our infection control requirements at 42 CFR 483.65(b)(2) state that ''The facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.'' The intent of this regulation is to prevent the spread of communicable diseases from employees to residents.

Influenza immunizations are given annually. ACIP (May 27, 1994) recommends that during October and November each year, vaccination should be routinely provided to all residents of chronic-care facilities with the concurrence of attending physicians. Consent is required for vaccination and can be obtained from the resident or their legal representative at the time of admission to the facility or anytime afterwards. When possible, all residents should be vaccinated at the beginning of the influenza season. Residents admitted after the influenza season begins, must be vaccinated at the time of admission until the end of March (ACIP, May 27, 1994). Therefore, we propose that all residents be offered immunization annually from October 1 through March 31. We hope to have this rule finalized by October 1, 2005, before the 2005–2006 influenza season.

PPV is given once in a life time, with certain exceptions. This proposed rule recognizes the exception by including language about a second shot at § 483.25(n)(2)(iv). This exception states, a second shot may be given 5 years after the first pneumococcal immunization if the vaccine was administered before age 65 and only according to a practitioner recommendation. The following is a simple algorithm ACIP recommends for pneumococcal polysaccharide vaccine.

FIGURE 1. Algorithm for vaccinating persons aged ≥65 years



*Note: For any person who has received a dose of pneumococcal vaccine at age ≥65 years, revaccination is not indicated.

For further information, please go to the CDC Web site listed below: *http://www.cdc.gov/mmwr/preview/mmwrhtml/00047135.htm#00001211.gif.*

Facilities must assess residents for medical contraindications before immunizing them to prevent complications and adverse effects. ACIP recommendations (February 8, 2002) state, ''contraindications and precautions to vaccination dictate circumstances when vaccines must not be administered. The majority of contraindications and precautions are temporary, and the vaccination can be administered later. For example, persons with acute febrile conditions should not be immunized until their fever subsides. A medical contraindication is a condition in a recipient that increases the risk for a serious adverse reaction. For example, administering influenza vaccine to a person with an anaphylactic allergy to egg protein could cause serious illness in or death of the recipient.'' The ACIP recommendations further state that one universal contraindication applicable to all vaccines is a history of a severe allergic reaction after a prior dose of vaccine or vaccine constituent.

If immunization is medically contraindicated, ACIP recommendations (2002) state that prophylactic use of antiviral agents is an option for preventing influenza among these persons. Persons who have a history of anaphylactic hypersensitivity to vaccine components but who are also at high risk for complications from influenza can benefit from the vaccine after appropriate allergy evaluation and desensitization. The report on the ''Use of Standing Orders Programs to Increase Adult Vaccination Rates,'' in the March 24, 2000 MMWR, states that standing orders protocols should also specify that vaccines be administered by healthcare professionals trained to (a) screen patients for contraindications to vaccination, (b) administer vaccines, and (c) monitor patients for adverse events, in accordance with State and local regulations.

It is important for facilities to remember that residents have the right to refuse immunization. However, educating residents and family members regarding the benefits of receiving immunizations generally results in consent.

III. Collection of Information Requirements

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

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements:

This proposed rule requires facilities to develop protocols or policies and procedures. 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 to document in the resident's medical record information concerning immunization history, contraindications etc. as a part of the process of immunizing residents. For example, the facility must indicate in the resident's medical record that the resident had received an influenza immunization, or that the vaccination was medically contraindicated, or that the immunization was refused. If the immunization was refused, documentation must include that the resident or the resident's legal representative received appropriate education and consultation regarding the benefits of influenza immunization.

The initial burden associated with these requirements in the first year, would be related to the establishment of policies and protocols for implementation of the immunization rule. This would be approximately 5 hours of a registered nurse's time per facility *i.e.* 80,695 hours for the first year (5 hours × 16,139 facilities). In subsequent years, we estimate that the burden associated with documentation of the immunization status of the resident in the medical records would be approximately 5 minutes of the registered nurse's time, which would be 134,492 hours per year (5 minutes per resident × 100 residents per facility × 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–P, 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–P, *Christopher Martin@omb.eop.gov*. Fax (202) 395–6974.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Waiver of the 60-day Comment Period

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. In accordance with section 1871(b)(1) of the Act, we routinely allow a comment period of at least 60 days on proposed rules that affect the Medicare program. This procedure can be waived; however, if an agency finds good cause that a 60-day comment period is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and its reasons in the rule issued. In accordance with section 1871(b)(2)(C) of the Act, we have shortened the comment period for this proposed rule from 60 to 15 days to allow us to hopefully finalize these provisions by October 1, 2005 in time for the 2005–2006 flu season. It is our view that a 60 day delay in receiving public comments on this proposed rule and publishing the subsequent 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 this proposed rule is published with a 60-day comment period it is highly unlikely that a final rule can be issued before October, and even if that were possible, nursing facilities would not have the lead time necessary to obtain resident and/or family consent. If expedited and published with a 15-day comment period, this delay can be prevented and the rule can be effective in the 2005–2006 flu season, with the potential of saving many lives.

We anticipate that the affect of this rule will be to increase immunization rates in nursing homes to 90 percent, which is the Healthy People 2010 goal. This will enable about half a million frail 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 27–35 percent reduction in mortality, and a 44–52 percent reduction in all-cause hospitalizations. Similarly, pneumococcal vaccination is associated with a 20–26 percent reduction in mortality, and a 12–28 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 proposed rule is published with a 15-day comment period so that a final rule can be published and effective in 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 proposed rule would be a vehicle to improve immunization rates and would be consistent with the Healthy People 2010 objectives.

We believe that a continued 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 comment period is unnecessary and contrary to public interest. We find on this basis, that there is good cause for waiving the 60-day comment period under section 1871(b)(2)(C) of the Act.

VI. Regulatory Impact

(If you choose to comment on issues in this section, please include the caption ''Impact Analysis'' at the beginning of your comment.)

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 proposed 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 proposed rule. It would not impose any mandates on State, local, or tribal governments, or the private sector that would 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.

As previously discussed in this preamble, this proposed rule would have a substantial 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 table 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
% 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 would 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 mid point 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 AND 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

In other rules, we have used an average value of a statistical life of $5 million to monetize the decreased mortality benefits of the rule. The population affected by this rule has different demographic and other characteristics from the populations that were addressed in these other rules. However, due to the lack of data on this specific population and in order to be consistent with previous rules, we are assuming a value of $5 million for the average value of a statistical life for this rule.

Therefore, since we estimate 2,304 lives will be saved by the influenza vaccination, we estimate the value saved from saving these lives as $11.52 billion.

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 is needed, for a person only needs to be immunized once in a life time. 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 deaths without increased immunizations	340	340	340	340	340	340
Number deaths following implementation of immunization regulation		260	244	228	212	196
Number lives saved due to pneumococcal immunization		80	96	112	128	144

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

LTC Residents	Current year	Projected				
		Year 1	Year 2	Year 3	Year 4	Year 5
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% 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	4,128,00	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).

** (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 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

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

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 IMPLEMENTATION RELATED TO THE IMMUNIZATION RULE

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

No. of LTC facilities	Hours spent per facility	Total burden hours	Total cost per agency
16,139	5 hours first year only	80,695 hours only first year	80,695 hours × $23.70 * = $1,912,471.

* $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 FOR BOTH IMMUNIZATIONS

[These expenses are annual]

No. of LTC facilities	Hours spent per resident per facility	Total burden hours	Total cost per agency
16,139	16,139 × 100 ** residents × 5 minutes = 8,069,500 minutes 134,492 hours.	134,492 hours	134,492 hours × $23.70 * = $3,187,460.

* $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 would 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 proposed rule except indirectly, through reduced utilization of care by individuals who do not, but would otherwise, require hospitalization.

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

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 would benefit from the implementation of this proposed rule. The various studies discussed are evidence that prevention of influenza and pneumonia would 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 reports 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 would 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 two to five 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 proposed rule would 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 proposed 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, 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 ensure that—

(i) Each resident is offered an influenza immunization between October 1 through March 31 annually, unless the immunization is medically contraindicated or the resident has

already been immunized during this time period; and

(ii) The resident or the resident's legal representative must be provided the opportunity to refuse immunization. If the resident or the resident's legal representative refuses immunization, the facility must ensure the resident or the resident's legal representative receives appropriate education and consultation regarding the benefits of influenza immunization.

(iii) The resident's immunization status is documented in the resident's medical record, including but not limited to; that the resident received an influenza immunization, or immunization was medically contraindicated, or immunization was refused. If the immunization was refused, documentation must include that the resident or the resident's legal representative received appropriate education and consultation regarding the benefits of influenza immunization.

(2) *Pneumococcal disease.* The facility must ensure that—

(i) Each resident is offered a *pneumococcal immunization,* unless the immunization is medically contraindicated or the resident has already been immunized; and

(ii) The resident or the resident's legal representative must be provided the opportunity to refuse immunization. If the resident or the resident's legal representative refuses immunization, the facility must ensure the resident or the resident's legal representative receives appropriate education and consultation regarding the benefits of *pneumococcal* immunization.

(iii) The resident's immunization status is documented in the resident's medical record, including but not limited to; that the resident received *pneumococcal immunization,* or immunization was medically contraindicated, or immunization was refused. If the immunization was refused, documention must include that the resident or the resident's legal representative received appropriate education and consultation regarding the benefits of *pneumococcal* immunization.

(iv) *Exception.* As an alternative, based on an assessment and practitioner recommendation, a second pneumococcal shot may be given after 5 years following the first pneumococcal immunization if the vaccine was administered before age 65, unless medically contraindicated or the resident or the resident's legal representative refuses the second shot.

(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: May 20, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 10, 2005.

Michael O. Leavitt,

Secretary.

[FR Doc. 05–16160 Filed 8–12–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

46 CFR Part 389

[Docket No. MARAD–2005–22050]

RIN 2133–AB67

Determination of Availability of Coastwise-Qualified Launch Barges

AGENCY: Maritime Administration, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Maritime Administration (MARAD, we, our, or us) is publishing this proposed rulemaking to establish regulations governing administrative determinations of availability of coastwise-qualified launch barges to be used in the transportation and launching of offshore oil drilling or production platform jackets in specified projects. This rulemaking implements provisions of the Coast Guard and Maritime Transportation Act of 2004, which, among other things, requires the Secretary of Transportation (acting through the Maritime Administrator) to adopt procedures to determine if coastwise-qualified vessels are available for platform jacket transport and launching, and, if not, to allow the use of non-coastwise qualified foreign built vessels.

DATES: Comments are due by October 14, 2005.

ADDRESSES: You may submit comments [identified by DOT DMS Docket Number MARAD–2005–22050] by any of the following methods:

- Web Site: *http://dms.dot.gov.* Follow the instructions for submitting comments on the DOT electronic docket site.
- Mail: Docket Management Facility; U.S. Department of Transportation, 400 7th St., SW., Nassif Building, Room PL–401, Washington, DC 20590–001.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 7th St., SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Instructions: All submissions must include the agency name and docket number for this rulemaking. Note that all comments received will be posted without change to *http://dms.dot.gov* including any personal information provided. Please see the Privacy Act heading under Regulatory Notices.

Docket: For access to the docket to read background documents or comments received, go to *http://dms.dot.gov* at any time or to Room PL–401 on the plaza level of the Nassif Building, 400 7th St., SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Michael Hokana, Office of Ports and Domestic Shipping, Maritime Administration, MAR–830, Room 7201, 400 7th St., SW., Washington, DC 20590; telephone: (202) 366–0760; email: *Michael.Hokana@dot.gov.*

SUPPLEMENTARY INFORMATION: Section 27 of the Merchant Marine Act of 1920, commonly known as the Jones Act (46 App. U.S.C. 883), requires, with a few exceptions, that all cargo transported in the coastwise trade be carried on ships that are U.S.-owned and U.S.-built. The Jones Act has been amended over the years, and in 1988 a special technical proviso, known as the thirteenth proviso, was added to allow for the use of foreign-built platform jacket launch barges in the coastwise trade if no U.S.-built vessels were found to be available.

On August 9, 2004, the thirteenth proviso of the Jones Act was amended by section 417 of the Coast Guard and Maritime Transportation Act of 2004, Public Law 108–293 (the Act). Under the Act, the Secretary of Transportation is directed to establish procedures to issue determinations as to whether suitable U.S.-built barges are available for use in transportation and launching (i.e., installation) of offshore oil drilling or production structures. The Act directs that if the Secretary determines, upon application by the owner/operator of a foreign-built barge, that a suitable U.S.-built barge is not reasonably available for use in a specified launch project, then the foreign-built barge may be used. Because the Bureau of Customs and Border Protection (CBP) is responsible for enforcing violations of the coastwise laws, MARAD recommends that applicants that receive a determination from MARAD further