

established by this rule is a reasonable one.

We also considered permitting a staff member to perform a patient assessment through telephone consultation with a physician or other LIP. Given the complexity of the patient population, we did not select this option. Physicians and LIPs are extensively trained in assessment of symptoms and behaviors, in physical examination and formulation of diagnoses and resulting treatment strategies. Staff who are onsite may have widely disparate assessment skills. Some hospitals may staff patient care areas with licensed practical nurses or other available staff. We are not persuaded that these staff members have the physical and psychiatric assessment skills that correspond to the medical complexity of a patient in crisis. Accordingly, we opted not to permit patient assessment through telephone consultation.

2. Effect on Beneficiaries

The implementation of the Patients' Rights CoP served to protect not only Medicare and Medicaid beneficiaries, but all patients receiving care in any of the 6,166 Medicare- and Medicaid-participating hospitals (that is, acute care, psychiatric, rehabilitation, long-term care, children's, and alcohol-drug) including small rural hospitals. Our goal is to safeguard against the mistreatment of all patients in these facilities including, but not limited to— (1) Deaths due to inappropriate restraint or seclusion use; (2) violation of patients' privacy and confidentiality in various aspects of the healthcare delivery process; and (3) systematic frustration of the patients' efforts to acquire his or her medical records. Patients benefit from the hospitals' focus on patients' rights. Through these protections, patient care can be delivered in an atmosphere of respect for an individual patient's comfort, dignity, and privacy. The interim final rule with comment period emphasizes the importance of staff training, adequate monitoring and assessment, and prompt evaluation of restrained or secluded patients. As these factors, lack of training, evaluation, monitoring, and assessment were involved in the deaths reported by the media, we believed that implementation of the Patients' Rights CoP would lead to a reduction in the number of restraint- and seclusion-related injuries and deaths in hospitals. The following chart represents the data that we have received from providers regarding deaths that may have been related to restraint or seclusion use:

Year	Number of Deaths
August 1999—December 1999 <sup>1</sup> .....	14
2000 .....	34
2001 .....	22
January 2002—March 2002 <sup>2</sup> .....	5
Total from August 1999—March 2002 .....	75

<sup>1</sup> The interim final rule with comment period was published on July 2, 1999 and effective on August 2, 1999. Therefore, no data on deaths related to restraint or seclusion use was submitted by providers before August 1999.

<sup>2</sup> The latest data available is through March 2002.

3. Effects on the Medicare and Medicaid Programs

We did not expect the implementation of the new Patients' Rights CoP to generate significant costs to the Medicare or Medicaid programs. We did not believe that there would be any additional costs to the survey and certification program as compliance with this new CoP either would be reviewed through a routine, nonaccredited hospital survey, a validation survey or as part of a complaint survey.

C. Conclusion

The Patients' Rights CoP introduced new Federal requirements that in many instances reflected existing State, accreditation or professional standards. These new Federal requirements are set forth in six standards to ensure minimum protections of each patient's physical and emotional health and safety. These standards address the patients' right to—

- Be notified of his or her rights;
- Exercise his or her rights in regard to his or her care;
- Privacy and safety;
- Confidentiality of and access to his or her medical records;
- Freedom from restraints used in the provision of acute medical and postsurgical care unless clinically necessary; and
- Freedom from restraint and seclusion use to manage violent or aggressive behavior unless clinically necessary.

(Catalog of Federal Domestic Assistance Programs No. 93.773, Medicare—Hospital Insurance and No. 93.778, Medical Assistance Program)

Dated: September 24, 2002.  
**Thomas A. Scully,**  
*Administrator, Centers for Medicare and Medicaid Services.*

Dated: September 26, 2002.  
**Tommy G. Thompson,**  
*Secretary of Health and Human Services.*  
 [FR Doc. 02-24857 Filed 9-27-02; 9:51 am]  
**BILLING CODE 4120-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Parts 482, 483, and 484**

[CMS-3160-FC]

RIN 0938-AM00

**Medicare and Medicaid Programs; Conditions of Participation: Immunization Standards for Hospitals, Long-Term Care Facilities, and Home Health Agencies**

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

**ACTION:** Final rule with comment period.

**SUMMARY:** The provisions of this final rule will remove the Federal barrier related to the requirement for a physician to order influenza and pneumococcal immunizations in Medicare and Medicaid participating hospitals, long-term care facilities, and home health agencies. This final rule will affect vaccine-preventable diseases and will help improve adult vaccination coverage rates. It will facilitate the delivery of appropriate vaccinations in a timely manner, increase the levels of vaccination coverage, and decrease the morbidity and mortality rate of influenza and pneumococcal diseases.

**DATES:** *Effective date:* These regulations are effective on October 2, 2002.

*Comment date:* Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on December 2, 2002.

**ADDRESSES:** In commenting, please refer to file code CMS-3160-FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission or e-mail.

Mail written comments (one original and three copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3160-FC, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received timely in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses: Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-14-03, 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 commenters 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 could be considered late.

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

**FOR FURTHER INFORMATION CONTACT:** Anita Panicker, RN, MS, LCSW, (410) 786-5646. Jeannie Miller, RN, (410) 786-3164.

#### **SUPPLEMENTARY INFORMATION:**

##### **Inspection of Public Comments**

Comments received timely will be available for public inspection as they are received, generally beginning approximately three 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, call (410) 786-7197.

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#### **I. Background**

##### *A. Conditions of Participation: Immunization Standards for Hospitals, Long-Term Care Facilities, and Home Health Agencies*

###### 1. Influenza and Related Conditions

Influenza and pneumonia combined represent the fifth leading cause of death in the elderly. The 1999 RAND report prepared for the Centers for Medicare & Medicaid Services (CMS), "Interventions that Increase the Utilization of Medicare-Funded Preventive Services for Persons Age 65 and Older," states that "influenza and consequent respiratory diseases are common causes of morbidity and mortality in the United States each year, with 20,000 to 40,000 deaths reported for each influenza epidemic. Over 90 percent of these deaths occur among those age 65 or older." The report also states that influenza vaccination "has been shown to be efficacious in the elderly, decreasing hospitalizations by 27 percent to 57 percent and deaths by 27 percent to 30 percent." (<http://www.cms.hhs.gov/healthyaging/2a.asp>.)

The Center for Health Research, a part of the Kaiser Permanente managed care organization, studied the cost-effectiveness of influenza vaccination over nine flu seasons in its northwest region in a study published in 1993. The study examined experiences of some 69,000 elderly members of the health maintenance organization who experienced 3,105 outpatient pneumonia and influenza episodes, 894 hospitalizations, and 113 pneumonia and influenza deaths. The estimated cost of providing a vaccination was \$7.11; average medical care costs for outpatient and inpatient episodes were \$106 and \$5,730, respectively, for high-risk elderly patients, and \$141 and \$4,477 for non-high-risk elderly patients. A similar study examined the cost-effectiveness of vaccinating elderly members of a Minnesota health plan against influenza over three seasons beginning in 1990. The plan, Group Health Inc. of Minneapolis, vaccinated 45 percent to 58 percent of its members over age 64. Vaccinated individuals had lower hospitalization rates for flu, pneumonia, congestive heart failure,

and other illness, for an average savings of \$117 per vaccinated member. ("The costly toll of vaccine-preventable disease." Business and Health; Montvale; 1995; (13)(3)16; Leavenworth, Geoffrey.)

Despite the availability of safe and effective vaccines and substantial progress in reducing vaccine-preventable diseases, improving the delivery of the vaccines is vital to further reduce and eliminate vaccine-preventable causes of morbidity and mortality. The administration of influenza and pneumococcal polysaccharide vaccines per standing orders, governed by the physician-approved policies and procedures of the facility or agency, after assessments for contraindications, is the most consistently effective method for increasing adult vaccination rates and the least burdensome to implement.

Influenza vaccine is the primary method for preventing influenza and its more severe complications. The Advisory Committee on Immunization Practices (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 who have chronic underlying medical conditions. Beginning with the 2000 to 2001 influenza season, the ACIP has added persons aged 50 to 64 years to the primary target group for annual influenza vaccination. This age group was added because a substantial proportion of persons aged 50 to 64 years (estimated at between 24 percent and 32 percent of the total population) have one or more chronic medical conditions that place them at high risk for influenza-related hospitalization and death. Rates of influenza-related excess hospitalization among adults younger than age 65 years old with one or more high-risk conditions have been estimated at 392 to 635 per 100,000 persons compared with 13 to 23 per 100,000 among those without high-risk conditions. There are minimal adverse reactions or side effects related to influenza vaccines because, as the Morbidity and Mortality Weekly Report (MMWR) states, "inactivated influenza vaccine contains noninfectious killed viruses and cannot cause influenza." The most frequent side effect of vaccination is soreness at the vaccination site that lasts less than 2 days. Fever, malaise, myalgia, and other systemic symptoms can occur but recent placebo-controlled trials demonstrate that among older persons and healthy

young adults, administration of split-virus influenza vaccine is not associated with higher rates of such systemic symptoms when compared with placebo injections. The potential benefits of influenza vaccination in preventing serious illness, hospitalization, and death greatly outweigh the vaccine reactions. ("Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP)." MMWR 51; RR03, (April 12, 2002) ("ACIP Recommendations"). The availability of safe and effective vaccines and substantial progress in the direction of reducing vaccine-preventable diseases has not produced the expected outcome, due to the lack of proper delivery in a timely manner to the targeted populations.

The Centers for Medicare & Medicaid Services and the Centers for Disease Control and Prevention (CDC) recognize the major impact of both influenza and pneumococcal disease on the residents of long-term care facilities, and the effectiveness of vaccines in reducing health care costs by preventing illness and hospitalization, and have collaborated to improve immunization coverage through standing orders. The goal is to immunize at least 90 percent of the institutionalized population to meet our Healthy People 2010 objectives through a national quality improvement program and to promote standing orders for immunization programs to ensure that all nursing facility residents are assessed for and offered influenza and pneumococcal vaccinations. (For more information on our Healthy People 2010 immunization goals and health objectives for the nation, in general, please see <http://www.health.gov/healthypeople>.) Standing orders programs authorize licensed practitioners, where allowed by State law, to administer vaccinations, after assessment for contraindications, according to a physician-approved facility or agency policy without the need for a physician's order. One of the key findings of the 1999 RAND report is that organizational changes are effective in improving the delivery of preventive services. Standing orders are a type of organizational change that allow appropriate non-physician staff to offer vaccinations, after assessment for contraindications, without an individual physician order, according to the facility or agency policy. The ACIP recommends implementing standing orders in nursing homes and hospitals. We have included home health agencies (HHAs) in this rule as providing vaccines in settings accessible to adults

is critical and the need to use transportation to reach a health-care provider is a barrier to receiving preventive services. This barrier may be eliminated by offering vaccines in such convenient locations as homes, where HHAs already provide other services.

## 2. Why a Change in the Conditions of Participation Is Needed

The Conditions of Participation (CoPs) are Federal requirements that establish basic health and safety standards that providers of health care services, such as hospitals and LTCFs, must meet in order to participate in the Medicare and Medicaid programs. However, the protection afforded by the Medicare and Medicaid CoPs apply to all patients regardless of payer source. Although the goal of the changes to the CoPs is to increase adult immunizations, the changes brought about by this rule could also be used by hospitals, HHAs, and LTCFs to implement immunization policies to improve flu and pneumonia immunization rates for children and adolescents.

The provisions of the final rule will remove the Federal barrier related to the physician's order requirement for influenza and pneumococcal immunizations in Medicare and Medicaid participating hospitals, long-term care facilities (LTCFs), and HHAs. Preventing morbidity and mortality due to severe influenza and its complications is one of the goals of this regulation. During the influenza season, hospitalization rates for high-risk populations increase two to five-fold, depending on the age group. 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. ("Prevention and Control of Influenza Indications for Influenza Vaccine." Disease Prevention News, Vol. 57, No. 20, September 20, 1997.) The proportion of elderly persons in the U.S. population is increasing, and age and its associated chronic diseases can increase the severity of influenza illness. Unless control measures are more vigorously implemented, the number of deaths from influenza and its complications is expected to increase.

According to the article, each year, more people die of pneumococcal pneumonia alone than die of breast cancer and AIDS combined. According to the CDC, an estimated 40,000 deaths annually in the United States are attributed to pneumococcal infection.

Immunization of high-risk persons could prevent up to half of these deaths. As of 1993, Medicare began reimbursing providers for influenza vaccine and its administration (<http://cms.hhs.gov/preventiveservices/2a.asp>). However, only 23 percent of one of the highest-risk groups, persons aged 65 years and older, had received vaccination against pneumococcal disease. Section 4107 of the Balanced Budget Act of 1997 "extended the influenza and pneumococcal vaccination campaign 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." Even with these changes in Medicare reimbursements, the rates of immunization did not improve as anticipated. A tragic example of these national trends occurred in Texas. In January 1997, a local health department alerted the Texas Department of Health to three laboratory-confirmed *Streptococcal pneumoniae* infections at a Northeast Texas nursing home with 90 residents. Pneumococcal vaccine had been administered to only 10 (11 percent) of the residents before the outbreak. The remaining nursing home residents were promptly vaccinated and given antibiotics to prevent further cases. However, two of the three patients with laboratory-confirmed infections died. A decade of use has confirmed the efficacy and safety of the current vaccine against pneumococcal disease. Moreover, the vaccine is inexpensive, and Medicare reimburses its cost.

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 the infection of others. However, despite the availability of safe and effective vaccines, substantial portions of susceptible adults are not being immunized. Our report in 2000 on the 1999 data indicate that 35 percent of the population age 65 or older has received the pneumococcal vaccine and 45 percent of the population age 65 or older has been immunized against the flu (<http://cms.hhs.gov/preventiveservices/2d.asp>). To reduce the morbidity and mortality rates, delivering appropriate vaccinations in a timely manner is vital. Maintaining high levels of vaccination coverage and low rates of vaccine-preventable diseases is the goal of this final rule. Standing orders will decrease vaccine-preventable diseases and improve adult

vaccination rates because they are the most consistently effective method for increasing adult vaccination rates and are easy to implement.

The report on "Use of Standing Orders Programs to Increase Adult Vaccination Rates" (MMWR 2000/49 RR01 15–26, March 24, 2000) (Standing Orders Report)), briefly reviews the evidence on the effectiveness of standing orders programs, describes standards for program implementation, and recommends initiating these programs to improve immunization coverage in several traditional and nontraditional settings. The report 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.

## II. Provisions of the Final Rule

### A. Conditions of Participation: Immunization Standards for Hospitals, Long-Term Care Facilities, and Home Health Agencies

The provisions of the final rule will remove the Federal barrier related to the physician's order requirement for influenza and pneumococcal immunizations in Medicare and Medicaid participating hospitals, LTCFs and HHAs, that have such a requirement. In developing a facility or agency policy for immunizing patients/residents, there must be input from the medical director or a physician. We discuss examples of core aspects of facility policy under the direction of the medical director or a physician below. However, this policy is not limited to these examples, and the specific circumstances of each beneficiary must be taken into account.

The most basic and vital aspect of facility policy must be patient assessment. Patient assessment is a mandatory element of professional practice standards for any procedure performed. This requirement, therefore, is not an exception, or a new practice

even though we wish to emphasize its importance here. Assessment of possible contraindications must be carried out before vaccines are administered. Inactivated influenza vaccine should not be administered, for example, to persons known to have anaphylactic hypersensitivity to eggs, or to other components of the influenza vaccine, without first consulting a physician. Prophylactic use of antiviral agents is an option for preventing influenza among these persons. However, 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. Information regarding vaccine components can be found in package inserts from each manufacturer. Similarly, persons with acute febrile illness usually should not be vaccinated until their symptoms have abated. However, minor illnesses with or without fever do not contraindicate the use of the influenza vaccine, particularly among children with mild upper respiratory tract infection or allergic rhinitis (ACIP Recommendations). The Standing Orders Report 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.

#### 1. Hospitals

We are changing the current requirements in the first sentence of our condition of participation for hospitals, at 42 CFR 482.23(c)(2), to read "All orders for drugs and biologicals must be in writing and signed by the practitioner or practitioners responsible for the care of the patient as specified under § 482.12(c) with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment for contraindications."

The September 2000 issue of the *Journals of Gerontology* includes an article that refers to a study that reviewed hospitals' data on influenza vaccination rates among hospitalized older adults that showed that in-hospital influenza vaccination rates for older adults were well below 5 percent ("Standing Orders for Influenza Vaccination Increased Vaccination Rates in Inpatient Settings Compared with Community Rates." The *Journals of*

*Gerontology*; Washington; Sep 2000; Vol. 55A; 9; M522–M526; Fiona Lawson; Vicki Baker; Dick Au; Janet E. McElhaney). The main barrier to vaccination was the requirement for a physician's order; other issues were that most of the medical staff did not view vaccination as a priority, or were concerned that vaccination might not be effective or might complicate the patient's course of treatment while in the hospital. Because an educational program was predicted to be ineffective for changing in-hospital practices of the attending staff, an influenza immunization program using a standing order under the principal investigator for the study was designed. The purpose of the study was to increase vaccination rates in this very high-risk group of hospitalized older adults. The result after implementation of the inpatient immunization program was an increase of 22 percent in the immunization rate. The study also found that in spite of many unvaccinated patients indicating that they would be vaccinated after discharge, only 1 percent were vaccinated in the community after discharge from the hospital.

Specific recommendations for hospital-based immunization were first published by ACIP in the 1980s—for influenza vaccine in 1986, and for pneumococcal vaccine in 1989. These recommendations were included in the Standards of Adult Immunization Practice that were issued by the National Coalition for Adult Immunization in 1990, and appeared in the second edition of the American College of Physicians' Guide for Adult Immunization (1990). Soon thereafter, hospital-based influenza and pneumococcal vaccination was recommended in the National Vaccine Advisory Committee's report on adult immunization and in a critical report published by the General Accounting Office. Subsequently, this strategy was included in the action plan for adult immunizations developed by the CDC and CMS, and was later endorsed by the Task Force on Community Preventive Services. It also was emphasized in a comprehensive report prepared for CMS by the RAND Corporation to provide evidence-based recommendations for increasing the use of Medicare-funded preventive-care services. ("Hospital-Based Influenza and Pneumococcal Vaccination: Sutton's Law Applied to Prevention," David S. Fedson, MD; Peter Houck, MD; Dale Bratzler, DO, MPH, Infection Control and Hospital Epidemiology, Volume 21(11) (692–699), November 2000.) (Fedson).

The most remarkable example of success with hospital-based

immunization is the program that was conducted at the Minneapolis Veterans Affairs Medical Center since 1984. This hospital-wide program initially focused on influenza vaccination of outpatients and used a combination of administrative, organizational, and patient oriented interventions. No specific attempts were made to involve physicians. Instead, the program was implemented by nurses according to a hospital policy that allowed them to vaccinate patients without a signed physician's order. By 1987, the program was vaccinating 60 percent of the hospital's elderly outpatients; by the late 1990s, almost 90 percent were regularly receiving influenza vaccine, most of them through the hospital's program.

Among successful programs for hospital-based influenza and pneumococcal vaccinations, a standing order is probably the most important feature. The ACIP has specifically recommended that standing orders be used to increase adult vaccination rates in all settings. Furthermore, none of the successful programs described thus far in the literature has depended on active physician participation. Instead, nurses or pharmacists have been responsible for their implementation. (Fedson, 692–699).

## 2. Long-Term Care Facilities

We are changing our current regulations in the Conditions of Participation for LTCFs at § 483.40 (b)(3) to read “the physician must sign and date all orders with the exception of orders for the administration of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved facility policy after an assessment for contraindications.”

There were 1,590,763 individuals over 65 years of age in LTCFs in the United States in 1990, and the number is estimated to grow to 2.9 million by 2020. (“Increasing Pneumococcal Vaccination Rates Among Residents of Long-Term Care Facilities: Provider-Based Improvement Strategies Implemented by Peer-Review Organizations in Four Western States.” Kurt B. Stevenson, MD; John W. McMahon, Sr, MD; Jan Harris, MSHA, CHE; J. Richard Hillman, MD; Steven D. Helgerson, MD, MPH. *Infection Control and Hospital Epidemiology*, Volume 21 (11) (705–710) November 2000). (Stevenson). A substantial increase in vaccination rates among such a large population will prevent a significant number of cases of influenza and pneumococcal bacteremia and related deaths. Standing orders appear to be one

intervention effective in sustaining successful vaccination efforts.

## 3. Home Health Agencies

We are changing the first sentence of the current requirements in the CoPs at § 484.18(c) for HHAs to read “drugs and treatments are administered by agency staff only as ordered by the physician, with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per agency policy developed in consultation with a physician, and after an assessment for contraindications.” HHA staff must include the immunization information on the patient's plan of care, although a physician's order is not required for influenza and pneumococcal vaccines.

Providing vaccines in settings readily accessible to adults who are most in need of the services is critical. For many adults, the need to use transportation to reach a healthcare provider is a barrier to receiving preventive services. This barrier may be eliminated by offering preventive services (for example, administration of vaccines) in convenient locations such as the patient's home. Eliminating the need for making an appointment in advance and avoiding the waiting time often associated with a clinic or office visit are factors that also might increase the opportunities for some adults to receive needed vaccinations. (“Adult Immunization Programs in Nontraditional Settings: Quality Standards and Guidance for Program Evaluation; A Report of the National Vaccine Advisory Committee.” MMWR 49 (RR01)1–13. March 24, 2000.)

The 1999 RAND report states that the proportion of the U.S. population over age 65 has 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. According to an October 1997 JAMA article, 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. (“Cost-effectiveness of Vaccination Against Pneumococcal Bacteremia Among Elderly People.” *JAMA*; Chicago; Oct 22–Oct 29, 1997; 278;16; Jane E Sisk; Alan J Moskowitz; William Whang; Jean D Lin; *et al.*)

## III. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, 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.

## IV. Waiver of Proposed Rulemaking

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. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and its reasons in the rule issued.

The delay in publishing this rule would be extremely detrimental to the health of beneficiaries, 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 older than 65 years of age 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 2002 to 2003 to decrease the risk of influenza state that the optimal time for influenza vaccinations is October through November. Therefore, it is imperative that this rule is published as a final rule immediately and the immunization process be implemented without delay this year so that influenza-related complications can be prevented. The goal of CMS and CDC, to immunize at least 90 percent of the adult population to meet the Healthy People 2010 objectives, can be attained earlier if the barrier requiring a physician's order is removed as soon as possible. Even though pneumococcal vaccines can be administered throughout the year the percentage of patients and or residents immunized remains low. Therefore, this final rule will be a vehicle to improve

coverage and will be consistent with the Healthy People 2010 objectives.

#### V. Waiver of Effective Date

We believe that a continued delay in implementation of this final rule would greatly hinder increased immunizations of beneficiaries in the affected facilities before the onset of this year's flu season. As a result, we have concluded that, in this instance, a notice-and-comment period, and a further delay in this rule's effective date is unnecessary and contrary to the public interest. We find, on this basis, that there is good cause for waiving the notice-and-comment period and for establishing this immediate effective date under 5 U.S.C. section 808(2).

#### VI. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, this document does not need to be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

#### VII. Regulatory Impact

##### A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any one year). This rule removes the barrier for an individual physician's order to be necessary to administer influenza and pneumococcal polysaccharide vaccines and is a requirement that has benefits in improving patient and resident health and in reducing health care spending. While it is not possible at this point to determine definitively the additional costs to the Medicare and Medicaid programs from increased immunizations resulting from this rule, we believe that the impact will be below the threshold

of \$100 million and will not be economically significant.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 to \$29 million in any one year. For purposes of the RFA, all hospitals, LTCFs, and HHAs, are considered to be small entities. Individuals and States are not included in the definition of a small entity. For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

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. This regulation does not have any impact on small rural hospitals that would be burdensome; instead rural hospitals will benefit from the implementation of the rule, as the overall cost associated with treating influenza and pneumococcal disease will be reduced.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This rule will not have any effect on the governments mentioned or on private sector costs.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates 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. This final rule will not have any effect on State or local governments. The costs related to the influenza and pneumococcal polysaccharide vaccines are currently a covered benefit for beneficiaries. In fact, this rule will

remove the barriers that may have impacted the flexibility of State law in implementing immunization related requirements.

##### B. Anticipated Effects of the Immunization Standards

###### 1. Effects on Hospitals, LTCFs, and HHAs

We expect that these providers will benefit from the implementation of this rule, as prevention of influenza and pneumonia will lower hospitalization rates, resulting in cost reductions.

###### 2. Effects on Other Providers

We do not expect the provisions of this final rule to affect other providers.

###### 3. Effects on the Medicare and Medicaid Programs

While it is not possible at this point to determine definitively the additional costs to the Medicare and Medicaid programs from increased immunizations resulting from this rule, we believe that, due to the low cost for the immunizations, any budget impact to these programs would be negligible. Moreover, increased immunizations may help reduce the estimated \$12 billion dollars in direct and indirect costs to society annually during severe influenza epidemics. Moderate epidemics cause more than 20,000 to 40,000 hospitalizations and estimated direct costs of up to \$1 billion per year. ("It Pays to Immunize Adults." Therese M. Droste. *Business and Health*; Montvale. Sep. 1998; 16; 8-11.) According to the 1997 JAMA article, the first pneumococcal polysaccharide vaccine was marketed in the United States almost 20 years ago, and two Federal studies have assessed its cost-effectiveness in preventing pneumococcal pneumonia in elderly people (*JAMA*; Oct 22-29, 1997; 278:1333-1339). In both analyses, vaccination was found to be cost-effective, that is, a reasonable investment for the health benefits gained. This article also states that even though savings cost is not the appropriate criterion for assessing an intervention, the issue is whether the investment in an intervention is worth the health benefits to be gained. Based on other interventions, policymakers have generally considered costs up to \$50,000 or even \$100,000 to be worth an extra year of healthy life. In that light, even worst-case estimates for pneumococcal vaccination through age 84 years would be deemed cost-effective.

In 2001, Medicare payments for flu and pneumococcal immunizations

totalled \$145,885,773. This figure represents Medicare payments for such immunizations furnished in all settings, including, but not limited to, hospitals, nursing homes, and HHAs. Immunization experts working under contract to CMS estimate that implementation of this rule will increase immunization rates by 10 percent. Therefore, we generally estimate that broad implementation of standing orders as allowed by this rule will increase Medicare immunization expenditures by \$14,588,577 above the 2001 expenditure.

These cost-effectiveness results provide a compelling case for clinical and public policy to more forcefully promote pneumococcal vaccination for elderly people in the United States. They thus add support on economic grounds to public and private efforts already under way. (JAMA; Oct 22-29; 1997; 278:16)

C. Alternatives Considered

1. Immunization Standards for Hospitals, Long-Term Care Facilities, and Home Health Agencies

An alternative would be to keep the present rules, as they are written. The current regulations, however, inhibit our ability to increase the rate of immunizations and to accomplish our goal to immunize at least 90 percent of the institutionalized population.

Another alternative would be to educate providers on the value of influenza and pneumococcal vaccines while maintaining the Federal barrier requiring a physician's order for every vaccine given in these provider types. Studies previously referred to, however, show that this has not been very effective in improving immunization rates.

D. Conclusion

Increasing the utilization of Medicare-funded 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.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 482

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

42 CFR Part 483

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

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

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

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

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

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

Subpart C—Basic Hospital Functions

2. In § 482.23, the first sentence of paragraph (c)(2) is revised to read as follows:

§ 482.23 Condition of participation: Nursing services.

\* \* \* \* \*

(c) \* \* \* (2) All orders for drugs and biologicals must be in writing and signed by the practitioner or practitioners responsible for the care of the patient as specified under § 482.12(c) with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment for contraindications. \* \* \*

\* \* \* \* \*

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. In § 483.40, paragraph (b)(3) is revised to read as follows:

§ 483.40 Physician services.

\* \* \* \* \*

(b) \* \* \* (3) Sign and date all orders with the exception of influenza and pneumococcal polysaccharide vaccines,

which may be administered per physician-approved facility policy after an assessment for contraindications.

\* \* \* \* \*

PART 484—HOME HEALTH SERVICES

1. The authority citation for part 484 continues to read as follows:

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

2. In § 484.18 the first sentence of paragraph (c) is revised to read as follows:

§ 484.18 Condition of participation: Acceptance of patients, plan of care, and medical supervision.

\* \* \* \* \*

(c) Standard: Conformance with physician orders. Drugs and treatments are administered by agency staff only as ordered by the physician with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per agency policy developed in consultation with a physician, and after an assessment for contraindications. \* \* \*

(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: July 23, 2002.

Thomas A. Scully, Administrator, Centers for Medicare & Medicaid Services.

Approved: August 28, 2002.

Tommy G. Thompson, Secretary.

[FR Doc. 02-25096 Filed 10-1-02; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 25

[IB Docket 99-67; RM 9165; FCC 02-134]

Petition of the National Telecommunications and Information Administration To Amend the Commission's Rules To Establish Emission Limits for Mobile and Portable Earth Stations Operating in the 1610-1660.5 MHz Band

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document the Commission adopts a new rule section,