Submitter : **Date: 08/24/2005**

Organization : **Ohio Department of Health**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow “Attach File” button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Dr. John Trowbridge** **Date: 08/24/2005**

Organization : **Dr. John Trowbridge**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

While the goal of increased percentage of immunization of at-risk populations has merit, my concern is whether the intention will be more coerced than merely offered. I strongly suggest that the proposal include an informed consent that would be used, so that it clearly states that individual choice will be recognized, that refusal of immunization carries no penalties or loss of benefits, that those who refuse might be at higher risk for contagious diseases for which the immunization might offer a certain protective benefit, and so on. If vaccinations were unreservedly accepted in the medical community, the situation would be less complicated. But there are serious questions of safety, side effects, and effectiveness -- and freedom of individual choice MUST be preserved and protected.
Thank you.
John Parks Trowbridge MD

Submitter : **Ben Parkinson** **Date: 08/24/2005**

Organization : **Ben Parkinson**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Seniors should not be forced to be immunized since they are free sovereign individuals who are capable of making their own decisions on such matters.

Submitter : **Dr. scott geller** **Date: 08/25/2005**

Organization : **south Fl. Eye Clinic**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Does anyone remember when President Ford got on TV to propagandize the masses into getting the Swine Flu vaccine, and how the manufacturers demanded liability protection?? Does anyone remember that the Swine flu never appeared on our shores? Does anyone remember the lives ruined because of Guillane=Barre syndrome caused by the vaccine that was supposed to protect them? Mass vaccination against the recent Asian Flu (with the preceeding 'shortage' gov/media hysteria) is for what purpose? Where is the Asian Flu in North America? Coercion of nursing home residents and their families (mere recommendation by government mandate constitutes coercion to a layman who cannot possibly understand all the implications and issues) will do more harm than good. Let the attending Physicians make the medical decisions. If innappropriate medical decision making then results in a pandemic, only then would Federal mandates be justified.

Scott Geller MD. Fort Myers, Florida

Submitter : **Mrs. Rosemary Johnson** **Date: 08/25/2005**

Organization : **Mrs. Rosemary Johnson**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

All people in this country have the right to make choices and this is true even for flu vaccinations. When presented with the option of receiving a vaccination it should be made clear that this vaccination is completely optional. All contraindications should also be presented in whatever manner is appropriate for the recipient. There should be no coercion in any form.

Submitter : **Ms. Ginger Shamblin** **Date: 08/25/2005**

Organization : **Tennesseans for Safer Vaccines**

Category : **Long-term Care**

Issue Areas/Comments

GENERAL

GENERAL

Until flu shots have been 'cleaned up' (at least the mercury & aluminum removed), it is madness to even administer them to long-term care patients. Why not, instead, invest in building immune systems with raw & fermented foods? After much research, I do not believe that the flu vaccines have any benefit. And it is well-documented that they can cause harm--even death.

Submitter : **Mrs. Donna Marton** **Date: 08/25/2005**

Organization : **Mrs. Donna Marton**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

While I see the potential benefits in mandating the flu vaccine in nursing home facilities, I cannot stress enough that each and every individual should be afford the right of WRITTEN informed consent. Such informed consent should include not only the benefits of the vaccine, but its risks should also be disclosed without bias. The resident or representative should be allowed to refuse the vaccine without fear of reprisal as well.

Submitter : **Date: 08/25/2005**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Forced vaccination of any American citizen is unconstitutional. Preying upon unsuspecting seniors whose care families have entrusted to long-term facilities to the financial benefit of pharmaceutical companies is criminal.

Please do your research before deciding on such a critical issue. Start by reading: THE MORAL RIGHT TO CONSCIENTIOUS, PERSONAL BELIEF OR PHILOSOPHICAL EXEMPTION TO MANDATORY VACCINATION LAWS by Barbara Loe Fisher, Co-Founder & President National Vaccine Information Center Presented to National Vaccine Advisory Committee May 2, 1997 at http://www.nvic.org/Loe_Fisher/blfstmt050297.htm

and learn more about the pharmaceutical industry and what the citizens of this country know:
Drug Companies Spend More on Lobbying Than Anyone Else

From the April 25, 2005 edition of USA Today comes an expose' story showing how much influence the pharmaceutical industry has over US lawmakers. The article starts by describing how drug companies allow their corporate jets to be used by politicians, and that the politicians are only legally required to pay the cost of a first class commercial flight.

In addition to flights and numerous other perks, the article chronicles the vast amount of money that the drug industry contributes to political candidates. They note that drug companies and their officials contributed at least $17 million to federal candidates in last year's elections. Additionally it was noted that they contributed nearly $1 million to President Bush and more than $500,000 to his opponent, John Kerry.

The Center for Responsive Politics, who keeps track of contributions, listed that in the year 2004 the drug companies spent $158 million dollars to lobby the federal government. They spent $17 million in campaign contributions in 2004 to federal candidates, and an additional $7.3 million in support for the 2004 political party conventions.

The article theorizes that the reasoning behind this scale of activity is that drug companies are heavily dependent on federal decisions. They note that it is the federal government that determines which products drug companies can market and how they're labeled. The article also pointed out that the government buys large quantities of drugs through Medicaid, the Veterans Administration and several other programs. When the new Medicare prescription drug benefit takes effect in 2006, the government will be paying 41% of Americans' drug bills, up from 24% at present.

Money also buys manpower. According to Amy Allina of the National Women's Health Network, 1,274 people were registered in Washington to lobby for drugmakers in 2003. Of that amazing number, some 476 are former federal officials, including 40 former members of Congress. Ms. Allina commented, "They are one of the strongest, most well-connected and most effective lobbies in Washington. Going up against them is more often than not a losing battle."
http://www.chiropracticresearch.org/NEWS_Drug%20Companies%20Spend%20More.htm

You are in a position of trust. Please don't betray that trust.
Thank you.

Submitter : **Mrs. Bina Robinson** **Date: 08/25/2005**

Organization : **CIVITAS - USA**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

I was pleased to note that the draft provided for individual's right to refuse the vaccine, but would like to see this option specifically provided for so there is less danger of its not being recognized.

This is particularly important because some vaccines still contain poisonous mercury as a preservative. Mercury can conribute to further debilitation in people who are already frail,

Thank you for reading.

Submitter : **Dr. Paul Kratka** **Date: 08/25/2005**

Organization : **Dr. Paul Kratka**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

1) The politics supporting vaccines, both emotional and financial, have replaced solid science. There is no good science supporting vaccinations, particularly flu vaccines, where the viruses number in the thousands and mutate each season.

2) Seniors are the most susceptible to adverse reactions to all vaccines, especially flu vaccines.

THIS IS A POLITICAL AND FINANCIAL SMOKESCREEN!!!

Submitter : **Dr. Sheri Skinner** **Date: 08/25/2005**

Organization : **N/A**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

I am a biomedical research scientist. The August 15 Federal Register announced the federal government's proposed regulation to withhold Medicare payments from long-term care facilities that do not provide (offer and recommend) flu and pneumonia vaccines to nursing-home residents. However, a clear, concise right respecting written informed consent is not delineated in the proposed rule. It is unacceptable to coerce any American citizen, let alone the most vulnerable among us, to accept treatment or vaccination in any form. A written and verbally communicated informed consent MUST be required before vaccination can be given and MUST include the risks as well as the benefits. This should be obvious. Please do not allow a punitive law such as this to be enacted without such basic protections for the residents of such long term facilities.

Submitter : **Mrs. Valerie Fermenic** **Date: 08/25/2005**

Organization : **Mrs. Valerie Fermenic**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

I strongly feel that our elderly and their care givers should have the right to refuse any vacinations. The last time I checked, this was still a free country although our freedoms are being taken away at an alarming rate. As the parent of a 22 old daughter who has been devastated by immunizations, I am appalled that our elderly not be given the right to choose.

Submitter : **Mrs. Barrie Galvin** **Date: 08/25/2005**

Organization : **Mrs. Barrie Galvin**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Do not require vaccine administration in nursing homes!

Sharing a personal story re flu vaccine availability in nursing homes..My mother was very toxic and I specifically requested that my mother not be given the mercury laden flu vaccine. Fortunately I had hired aides to be present to assist with feeding issues, but they were not paid to be there all day long. And one day, while the aide was fortunately with my mother, the nurses came to administer the flu vaccine and argued with the aide that my mother MUST have it. The aide reached me by phone (I had both health and general power of attorney)because she remembered that I told her that I had asked that my mother was not to get that vaccine. Only because the aide was present and informed was I able to have our wishes honored. This incident occurred in a respected Cleveland facility. I have grave concerns over requiring any vaccine in such an environment where staff is often hurried, understaffed, using substitute contracting agency people and often uninformed about specific patients. Last years data proves that the vaccince was not effective. I do not agree that any vaccine should be required by our govt. let alone in an environment where patients are often unable to advocate and protect themselves.

Barrie G. Galvin
Clinical Director, Therapy Services
Barrie G Galvin and Assoc LTD

Submitter : **Mrs. Myra Lowrie** **Date: 08/25/2005**

Organization : **N/A**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

My mother who has terminal cancer DID NOT get a flu shot last year for the first time in many years and felt better than she has ever felt. She does not want anymore flu shots because she realizes the flu shot actually made her feel badly. I am 54 and I had a flu shot once and was sick for days. Two of my best freind lost elderly parents just hours following flu shots. I want a chance to say no to a flu shots as I age.

Submitter : **Mr. russell emerson** **Date: 08/25/2005**

Organization : **Mr. russell emerson**

Category : **Other**

Issue Areas/Comments

GENERAL

GENERAL

TAWHOMEVER IT MAY CONCERN ,
Coercion of any kind is wrong at any time . It is however right that residents or their legal/ medical proxy , be informed of the residents right to refusal .
emersonrussell@yahoo.com

Submitter : **Dorothy Weber** **Date:** **08/25/2005**

Organization : **Dorothy Weber**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

Informed consent must accompany all vaccinations and there must be no coersion.

Submitter : **Mrs. V H** **Date: 08/25/2005**

Organization : **Mrs. V H**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

FLU vaccine should ALWAYS be a CHOICE for both the patient and the STAFF.
No one should be FORCED to participate in a program which may harm them.
We regulate MUCH TOO MUCH in our GOVT. WHY not just say we are a SOCIALISTIC GOVT and be done with it. NO I BELIEVE IN FREE CHOICE EVEN WITH HEALTH!
VJH

Submitter : **Date: 08/26/2005**

Organization :

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Subject: Mass Flu shots don't help elderly - unless they are shareholders

ORLANDO SENTINEL February 15, 2005 Robyn Shelton - Medical Writer

?Vaccinations have risen dramatically since 1968, but death rates are stable, experts say. There is no evidence flu vaccines help elderly Americans avoid death from the disease, according to a study released Monday that tracked flu mortality rates during a 33-year period.?

NOTE: The CDC admits that only 20 percent of all flu-like illness in any given flu season is actually caused by an influenza virus. (Source: B.L. Fisher ex-FDA Vaccine Advisory Board)
Why, then, are you aiding and abetting the pharma companies? We, in Australia, will also follow your dangerous and fruitless recommendations (some die from the vax - accoding to your Adverse Reactions Reporting). American medicine is now the No.1 'cause of death' (see Dr Gary Null et al. white paper from J. Public Health). This is a financial plan, not a health plan.

Submitter : **Ms. Anne Cicero** **Date: 08/26/2005**

Organization : **Ms. Anne Cicero**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Take out the mercury and other poisons out of the immunizations before you force people to take them. PLEASE take them out of the children's vaccinations also! Why would you want to create more medical problems? Oh, ya, to keep the physician's with plenty of work and the drug companies happy. Forced medicine is socialistic.

Submitter : **Marla Sgarbossa** **Date: 08/26/2005**

Organization : **Marla Sgarbossa**

Category : **Critical Access Hospital**

Issue Areas/Comments

GENERAL

GENERAL

The government should not refuse aid to Nursing homes that do not fully vaccinate their patients. I do not believe that the government should have the authority to dictate that someone recieve a flu vaccine. It is an individuals right to make the choice of what should or should not be injected into their body. A nursing home patient may not understand the complications associated with the flu vaccine. The government needs to allow individuals to make thier own decisions and stop applying pressure. Whose interest is at stake???

Submitter : **Mrs. Virginia Young** **Date: 08/26/2005**

Organization : **Mrs. Virginia Young**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-3198-P-21-Attach-1.DOC

Re: filecode CMS-3198-p

August 25, 2005

I am writing in reference to filecode CMS-3198-p and I would like to briefly share my family's personal experiences and comment on the proposed rule for the record.

Thankfully, my mother never needed a nursing home, but she did use Medicare. She felt she didn't need the flu shot, but her physician convinced her to take one for several years. When she fell ill within a week or two of the vaccine, as she always did following vaccination, she was told by her physician that the illness would have been worse if she had not taken the shot. Four years ago she not only fell ill with the flu, but she was plagued with episodes of "floaters" in her eyes, dizzy spells, fatigue, and memory loss afterwards. She could not fully recover from the cough and fatigue and appeared to suffer from allergies as well. She had been an unusually active, healthy, and independent lady. Concerned by the unusual and sudden changes my mother sought medical advice. She appeared to be healthy and was told she was "just getting old". A thorough and extensive physical confirmed her health prior to the injection yet the physician simply denied any association between illness and the vaccine because the vaccine is "safe and cannot cause the flu".

The following Spring I received an urgent call from her neighbor. She had driven my mother to a prominent hospital in the Texas Medical Center. I told her I would come right away as the neighbor had other urgent matters to tend to but did not want to leave my mother alone in the Emergency Department. I had an hour-long drive ahead of me and hoped the ER could give me some information over the phone. Of course they could not tell me much for reasons of confidentiality. When I explained that I was the only family member able to come to the hospital and was stuck in traffic they eventually told me that she had been released to her daughter. I am her only daughter.

Upon arrival at my mother's home I discovered her in obvious pain in the fetal position on her couch. She could say very little as she rocked and moaned in pain. She was able to tell me that she was sent home in a cab. The hospital thoroughly checked her heart, but somehow missed her head and neck where the majority of pain was located. With the help of friends I was able to get her some care. Follow up of her chronic cough showed an unusual pneumonia and a pulmonary effusion, which puzzled the pulmonary specialist. She was followed for many months until her lungs cleared. That year she decided to discontinue the use of the flu shot despite continued pressure to take it. She never had the flu again. She had never had serious trouble with the flu prior to the vaccination. My mother died last year of a massive basal ganglion hemorrhage. Review of her medical records show that much was missed. An MRI was never performed despite her requests and complaints of trouble with vision, memory loss, fatigue, and pain in the head and neck. She fell ill with vaccination but it was never recorded or reported.

I see no provision for informed consent in your proposal, only for educating the patients on the "benefits" of the vaccine. It appears the nursing homes are being strong-armed into pushing the vaccine by holding their Medicare provider status over them. In Texas nursing homes are already required to

offer the vaccine. Our legislature decided against forcing the vaccination and I have serious concerns about where the federal government is headed with this rule as far as our state's rights are concerned.

As far as the pneumococcal vaccine is concerned, I am aware of several contraindications, precautions, and interactions, which historically have been disregarded costing some individuals their lives. Patients with severe cardiac and/or pulmonary disease are at greater risk of complications from the vaccine. I have found that rarely is a nursing home patient free of significant cardiopulmonary disease. According to the manufacturer of Pneumovax 23 "pneumococcal infection in the preceeding three years" and "any active infection" are reasons to defer injection. The fact that pre-existing antibodies may result in increased anaphylactic reactions is well established. Children have been given repeat doses of this vaccine and suffered severe reactions resulting in death. Often the patients cannot remember their own medical history and neither can their children. It is simply not possible to ensure the patients' safety in this scenario.

A decreased effect with other live vaccines, immunoglobulin, and immunosuppressive agents is also noted, and as with all vaccines no studies have been performed to test for carcinogenic, mutagenic, or teratogenic effects. These vaccines are made by humans and used by humans, therefore human error cannot be avoided. The policies mandating vaccines, the methods by which vaccines are administered, and the post-marketing surveillance are flawed. No human should be forced to participate in such a dangerous system and the fact that our tax dollars are used to jeopardize unsuspecting and innocent lives is an outrage.

Common sense tells us that the elderly are more prone to disease and complications from disease. I have volunteered in nursing homes and many of my friends have family members in nursing homes. If the CMS, CDC, Department of Health and Human Services and any other related organization would like to help prevent disease and suffering in our elderly population our tax dollars would be put to better use in other areas.

Thank you for your time.

Sincerely,

Virginia Young

Cc Senator Cornyn, Congressman Brady, Sen. Tommy Williams, Rep. Rob Eissler, Kathi Williams, Barbara Loe Fisher, Dawn Richardson, Rebecca Rex, Donna Wick

Submitter : **Ms. Caroline Larson** **Date: 08/26/2005**

Organization : **Fairport Baptist Homes**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow “Attach File” button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Ms. Gail Sacelaris** **Date: 08/27/2005**

Organization : **Ms. Gail Sacelaris**

Category : **Comprehensive Outpatient Rehabilitation Facility**

Issue Areas/Comments

GENERAL

GENERAL

Background: Please be advised that any immunizations that are required by the government for long-term facilities should not be passed. We as Americans must have the right to say what goes into our bodies. We as Americans need to make our own choices and be accountable for our own lives and health. It is umbelievable that a government will dictate whether or not we choose to partake in an immunization based on Drug companies and any participating party benefiting from this money is more important than the health of our elderly. I do not recommend this and am against any type of mandated immunication standard for Long-Term Facilites.

Submitter : **Ms. Koreen Bowers** **Date: 08/28/2005**

Organization : **Ms. Koreen Bowers**

Category : **Long-term Care**

Issue Areas/Comments

GENERAL

GENERAL

I am frustrated that you would consider linking nursing-home payments to vaccinations. As we are finding out, not only are they not necessarily safe or effective, it tramples over all of our rights to choose our own health care and what's best for each patient. Butt out!

Submitter : **Ms. barb sachau** **Date: 08/28/2005**

Organization : **Ms. barb sachau**

Category : **Other**

Issue Areas/Comments

GENERAL

GENERAL

dhs center for medicate - rin 0938-an95 mandating vaccines like flu be given to long term care people

i oppose any mandatory vaccination of flu vaccine to anyone who does not want it.

i think the govt is simply making drug mfrs. richers by mandating all of these vaccines. I think that is behind this awful increase in putting drugs into everyone with no good reason. greeed!

i also know that immigrants with bad health are causing many of these problems since nobody checks the health status of the illegal alien criminal overwhelming usa. our govt has made all of us sitting ducks for any disease brought in by an immigrant.

Submitter : **Dr. Daniel Duffy** **Date: 08/28/2005**

Organization : **Dr. Daniel Duffy**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I do not think the government should be in the business of advising anyone to submit to any type of vaccine for any reason under any condition or circumstance. The only role the government should play in disease prevention is a demand for quarantine for a specified, limited time period for a specific reason demanded by absolute evidence for its necessity. Vaccination is the quintessential form of medical quackery in our day and age and is causing untold damage to health, well being and prosperity for all except those who profit from its use.

Submitter : **Roman Bystrianyk** **Date: 08/29/2005**

Organization : **Roman Bystrianyk**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Roman Bystrianyk, "Flu vaccines for all nursing home patients?", Health Sentinel, August 29, 2005,

The Centers for Medicare and Medicaid Services (CMS) has put forth a proposal to provide flu and pneumococcal vaccines to all nursing home residents that are under the Medicare and Medicaid programs. Unless refused by the patient or patient?s family or for medical reasons, nursing homes would be required to ensure that each resident received the immunizations as a condition of participation in the two programs.

According to the CMS website, ?About two million Americans, most age 65 years or older, live in long-term care facilities. People aged 65 years and older account for more than 90 percent of influenza-related deaths in the United States and elderly nursing home residents are particularly vulnerable to influenza-related complications. In addition, the elderly are more likely than younger individuals to die from pneumonia.?

According to the proposal listed in the August 15, 2005 Federal Register, ?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.?

However, the proposal notes that a February 14, 2005 study published in the Archives of Internal Medicine found that, ?vaccination of the elderly population against influenza may be less effective in preventing death among the elderly than previously estimated.? In fact, this study examined the influenza related deaths in the entire US elderly population. The authors expected that since influenza vaccination had greatly increased over the last 25 years that there would be a reduction in mortality by about 35% to 40%. What they found instead was no reduction in death despite increased vaccination and concluding, ?these estimates, which provide the best available national estimates of the fraction of all winter deaths that are specifically attributable to influenza, show that the observational studies must overstate the mortality benefits of the vaccine.?

Why did this study differ so greatly from the generally stated benefit?

According to the study, ?an immunologic study that found antibody responses following influenza vaccination decline sharply after age 65 years and a clinical trial involving subjects 60 years or older that the efficacy of the influenza vaccine in preventing illness was lower in people older than 70 years.? They also conclude, ?Some or all of the reduction in all-cause mortality in other observational studies was not attributable to vaccination but rather to underlying differences between vaccinated and unvaccinated cohorts.? This means that the authors believe that the studies that found a benefit were flawed in how they chose the people that participated in the study.

Taking the raw mortality data from a number of sources and plotting them versus vaccination rates I arrived at similarly interesting results (http://www.healthsentinel.com/graphs.php?id=67&event=graphs_print_list_item). In 1979 the mortality rate was approximately 21 per 100,000. By 2002, the rate had increased to 37 per 100,000. During the same time period influenza vaccination rates had gone from 20% of the population to approximately 65% of the population. Contrary to general assertions the mortality rate increased during the time vaccination rates had increased. However, through an email exchange with the lead author of that February 14, 2005 study, Dr. Simonsen, she noted that after adjusting for an increasingly aging population and for changes in circulating influenza strains that the increase became a flat trend. That is to say there was no change at all despite a 50% increase in influenza vaccinations.

Continued at: http://www.healthsentinel.com/org_news.php?event=org_news_print_list_item&id=053

Submitter : **Ms. DONNA THOMAS** **Date: 08/24/2005**

Organization : **FORMER ARKANSAS STATE LPN STUDENT**

Category : **Other**

Issue Areas/Comments

GENERAL

GENERAL

FORMER STUDENT NURSE 1992 WHO DID POSTMORTEM CARE ON A NURSING HOME PATIENT WITHOUT BEING VACCINATED FOR HEPATITIS B VACCINE THAT WAS MANDATORY FOR HEALTHCARE PERSONNEL.

NOT COVERED BECAUSE STUDENTS ARE GUESTS IN THE FACILITY NOT PERSONNEL..

I am the Donna K. Thomas who filed JC 94-269 THOMAS VS. ARKANSAS STATE UNIVERSITY et al. and JC 95-179 Thomas vs. Robert B Reich, Secretary of Labor attempting to get HEALTHCARE PROFESSION STUDENTS coverage under the BLOODBORNE PATHOGEN STANDARD that was enacted in 1992, the year I was a student nurse. There is no provision for us because our instructors signed a contract waiving pay for clinical hours. Yet Medicare and Medicaid are billed full price for services performed by unpaid workers who borrow money to attend school and work clinical hours. A tax break was given to student doctors so that the hospitals do not have to pay FICA tax. Apparently student lives have no value until they graduate. They are ony the first stop for blood drives.

DOES BLOOD ONLY SPLATTER on supervisors?

DO THEY NOT need to be vaccinated for HBV BEFORE they graduate IS THERE only minimal exposure to the body fluids of a baby when they are on an OB/lLABOR/DELIVERY ROTATION OR GIVING AN EPINEPHRINE INJECTION OR DRESSING A WOUND IN THE ER. OR ADMINISTERING A FEEDING TUBE FEEDING IN ICU.

IF TAXPAYERS DO NOT MIND SUBSIDIZING THIS since 1973 when an emergency provision was scheduled to sunset, fine. Medicare andMedicaid need to maintain funding levels to prevent a healthcare crisis, IF STUDENTS WORK CLINICAL HOURS FOR FREE WITH NO OSHA PROTECTION THEN THE SERVICES SHOULD BE FREE.

Submitter : **Ms. Rochelle Archuleta** **Date: 08/29/2005**

Organization : **American Hospital Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-3198-P-29-Attach-1.DOC

August 30, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

Ref: CMS – 3198 – P; Medicare and Medicaid Programs; Condition of Participation: Immunization Standard for Long Term Care Facilities

Dear Dr. McClellan:

The American Hospital Association (AHA), on behalf of our 4,700 member hospitals and health care systems, and our 31,000 individual members, including 1,200 skilled nursing facilities (SNF), appreciates the opportunity to comment on the proposed changes to the Medicare and Medicaid conditions of participation (COP) for nursing homes and SNFs. This proposed rule would require that nursing homes and SNFs provide influenza and pneumonia vaccinations to patients and document immunization status in patient medical records, unless the vaccine is medically contraindicated or refused by the patient. The AHA strongly supports this proposal to ensure that this vulnerable population of patients receives the benefit and protection of influenza and pneumonia immunizations. We are pleased to assist CMS in promoting this proposal.

While we applaud CMS' proposal, several operational issues raise concerns. As demonstrated in the fall of 2004, the vaccine supply is beyond the control of providers. If a shortage or major delay in vaccine supply occurs, providers should not be penalized by CMS or state survey agencies monitoring compliance with this new requirement. Therefore, we recommend that the final rule state that if a shortage or substantial delay in vaccine supply occurs, then SNFs and nursing homes will be automatically exempt from compliance with this COP during the shortage period.

As is widely recognized, the continuity of medical records between the acute setting and post-acute and nursing home settings is highly variable. Following a stay in a general acute hospital, or when being treated for an advanced chronic condition, many Medicare patients receive care in more than one post-acute setting, with some also receiving residential services in a nursing

home. Often, these patients have a distinct medical record with each provider. Unfortunately, there is no reliable, efficient mechanism for integrating or coordinating the contents of the various records. In

addition, attempts to access the contents of medical records stored by other providers can be time consuming and difficult. Frequently, patients are expected to be able to share accurate contact information for prior sites of care – an unrealistic expectation in some circumstances. Given these challenges, CMS should consider implementing a mechanism for patients, or their representatives, to state whether they have already received an influenza and or pneumococcal immunization, within the recommended timeframes. This would minimize the occurrence of redundant vaccines, minimize unnecessary costs, and avoid wasting vaccines and exacerbating any vaccine shortages.

In addition, CMS should ensure that any penalties for noncompliance with the immunization documentation requirement are not excessive, given the systemic burdens faced by nursing homes and SNFs attempting to determine whether an annual influenza immunization or a lifetime pneumococcal immunization were provided in a prior setting.

The AHA appreciates the opportunity to submit these comments. If you have any questions, please contact me or Rochelle Archuleta, senior associate director for policy, at (202) 626-2320.

Sincerely,

Rick Pollack
Executive Vice President

Richard Baer, MD
March 3, 2004
Page 2

Mark B. McClellan, M.D., Ph.D.
August 30, 2005
Page 2

Submitter : **Mr. David Schulke** **Date: 08/29/2005**

Organization : **American Health Quality Association**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3198-P-30-Attach-1.DOC

August 30, 2005

Mark McClellan, MD
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

File Code: CMS-3198-P

Dear Dr. McClellan:

The American Health Quality Association (AHQA), representing the national network of Medicare Quality Improvement Organizations (QIOs), is pleased to provide comments on the proposed rule for "Conditions of Participation: Immunization Standard for Long Term Care Facilities" published in the Federal Register of August 15, 2005.

"I. Background"

AHQA strongly supports efforts to educate health care providers, practitioners and patients about the health benefits of influenza and pneumococcal immunizations, unless contraindicated or refused by the patient. Although the proposed rule cites numerous studies documenting gaps in immunizing nursing home residents and staff, there is still no comprehensive, reliable source of immunization data for these populations.

Recommendation 1: CMS should create a system that ensures that accurate immunization information is captured for all residents and staff and ensure that any such measure of performance based on this data is valid.

We understand that resident immunization information will be collected as part of MDS 3.0. Once implemented, MDS 3.0 should become the primary data source for tracking resident immunizations and should be used to develop a measure, backed by the National Quality Forum's consensus process, that is suitable for internal quality improvement and public accountability.

In particular, CMS should ensure that the MDS data is linked with a larger database that tracks patients' immunization information prior to their nursing home admission. Relying solely on patients to convey their immunization information is inadequate, as few individuals, particularly frail nursing home residents and their families, can provide reliable information on immunization status. In addition, the database and subsequent measure should exclude instances of resident refusal to receive immunizations, as long as the vaccine was offered and the offer was documented.

"II. Provisions of the Proposed Rule"

QIOs have worked with hospitals, ambulatory care providers and community partners with direct access to beneficiaries, including underserved populations, to increase utilization of immunizations covered by Medicare. QIOs achieved considerable success increasing vaccination rates for flu and pneumonia in the hospital-setting during the 7th Statement of Work (March 2002-July 2004):

* Influenza Immunization: Improved from 13.8% to 42.78%, which is a 23.20% reduction in the failure rate.
* Pneumococcal Immunization: Improved from 16.49% to 41.59%, which is a 26.20% reduction in failure rate.

These results indicate the substantial improvement possible when QIOs and facility-based providers work collaboratively to improve quality, as well as the value of publicly reporting quality data on provider performance, which drives providers to seek assistance for improvement and to make necessary changes that produce results. AHQA supports the powerful combination of technical assistance and incentives (financial and non-financial) for improving quality. Therefore, we are concerned that regulations alone, as proposed in this rule, will not be sufficient in achieving the HHS goals for significantly increasing immunization rates among nursing home residents and staff.

Recommendation 2: CMS should direct QIOs to increase immunization rates among nursing home residents and staff as part of the core activities in the QIO Statement of Work (with necessary additional funding apportioned for these efforts).

Recommendation 3: CMS should incentivize high performance on valid, consensus-backed measures of resident and staff immunizations by posting performance information on Nursing Home Compare and including such measures as part of any long-term care pay for performance initiative.

AHQA appreciates the opportunity to comment on this important matter. Please contact myself or Dave Adler (dadler@ahqa.org; 202-261-7572) with any questions regarding these comments.

Sincerely,

David G. Schulke
Executive Vice President

2

Advancing the Safety and Quality of Health Care Nationwide

Submitter : **Joel Greene** **Date: 08/29/2005**

Organization : **Extendicare Health Services, Inc.**

Category : **Long-term Care**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3198-P-31-Attach-1.DOC

August 26, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445 – G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington D.C. 20201
Attn: CMS-3198-P

Re: Comments on Medicare and Medicaid Programs; Conditions of Participation: Immunization Standard for Long Term Care Facilities, Proposed Rule, 70 Federal Register 47759, August 15, 2005, CMS 3198-P

Dear Dr. McClellan:

Extendicare Health Services, Inc. (EHSI) appreciates the opportunity to comment on the proposed rule , Immunization Standard for Long Term Care Facilities, Proposed Rule, 70 Federal Register 47759, August 15, 2005, CMS 3198-P. EHSI is one of the nation's leading providers of skilled nursing home care with 148 facilities in eleven states with the capacity to serve almost 15,000 patients. EHSI as a member of The American Health Care Association and Alliance for Quality Nursing Home Care is committed to Quality First in the support of quality, affordable long term care.

We compliment CMS on its initiative to promote an effective program of immunization against influenza and pneumococcal virus in an effort to decrease morbidity and mortality from these diseases. While we are highly supportive of a vaccination initiative we are strongly opposed to a regulatory approach and the costs and administrative burden inherent in the regulatory approach. Extendicare is supportive of and an active proponent for voluntary approach. We offer vaccination for influenza and pneumonia and provide notices regarding the availability of the vaccines in multiple languages. As the vaccine is billable under Medicare Part B there is no cost to the provider or Pt B eligible patient.

The mandatory approach as proposed by CMS is problematic and EHSI has several concerns. In the background information on the proposal, CMS reported that in 2003, 66.4 of nursing home patients were vaccinated. CMS did not provide statistics on the number for whom vaccination would be contraindicated or for those that refused inoculation. Lacking data from CMS and given the health status of many nursing home residents an estimate of 20% for refusals and contraindicated patients is not unreasonable, which leaves only 14% unaccounted. This is not a sufficient percentage of patients upon which a mandatory policy should be based.

CMS did not discuss the potential of liability issues for allergic reactions when medical record data is not clear and a responsible party is not reasonably available, particularly with dementia patients.

There appears to be no input from state agencies on the proposal. Enforcement would appear to be a state responsibility; CMS did not appear to have discussed the issue of enforcement with state agencies to garner their concerns or support prior to publication as proposed.

CMS has failed to give consideration to current and future voluntary provider initiatives to vaccinate patients. What are the costs and benefits of a voluntary initiative as opposed to intrusive mandate? CMS may better serve the provider and patient community by assuring that an adequate supply of vaccine is available on a timely basis. Further, the health care community may be better served if CMS made vaccine available to health facility employees that have direct patient contact. Inoculation of employees that may serve as conduits and with improved public service announcements regarding precautions to be taken by visitors to health facilities may significantly reduce exposure rates and should be a first line of control.

CMS has significantly understated the fiscal impact of this initiative. Per section lll on page 47765, column 1 about ¾ down the column, CMS presented a statistical analysis of the management cost of the initiative per facility. This analysis appears to be flawed as it is based upon patient days as opposed to the number of admissions. Extendicare facilities admit an average of 10.5 patients per month; this would require the average facility with 100 patients to vaccinate 163 patients as opposed to the 100 estimated by CMS. Applied to 16,139 facilities would yield more than 2.6 million patients to be vaccinated. The estimated time to for record keeping is understated; 5 minutes per patient with an average wage of $20 per hour would cost the system $4.4 million in resources. It is likely to take more than 5 minutes per patient because of the need to track down medical records and obtain information and permission from patients' responsible parties. The estimated time could double. Even at 5 minutes the cost is equal to one quarter of the funding that CMS recently added back to the Medicare system in the recent RUG refinement initiative.

Given these concerns, Extendicare believes that CMS would better serve the skilled nursing patient by supporting a voluntary program that ensures an adequate and timely supply of vaccine and support inoculations for staff and visitors to deter the spread of these diseases into the facility.

Sincerely

J. Mark Greene
Director of Reimbursement Policy
Extendicare Health Services, Inc.

111 West Michigan Street Milwaukee, Wisconsin 53203-2903 (414) 908-8000

Submitter : **Mr. Stephen Wada** **Date: 08/30/2005**

Organization : **Hawaii Health Systems Corporation**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

Will CMS provide some relief if adequate quantities of vaccines are not available due to a nation wide shortage such as the recent shortage of the flu vaccines?

Submitter : **Sharon Macey** **Date: 08/30/2005**

Organization : **Sharon Macey**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

Concerning the HHS suggestion to forcibly vaccinate nursing home occupants?

Forced vaccination policies, which apply social, educational, and financial sanctions against citizens who do not comply, violate the human right to make informed, voluntary decisions about risks which involve serious injury and death.

Submitter : **Mr. JAMES MARX** **Date: 08/30/2005**

Organization : **Mr. JAMES MARX**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-3198-P-34-Attach-1.DOC

August 29, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3198-P
PO Box 8010
Baltimore, MD 21244-8010

Comments on Immunization Standard for Long Term Care Facilities

Dear Sirs:

Thank you for the opportunity to comment on proposed changes to the CMS Conditions of Participation for Long Term Care Facilities- Immunization Standard for Long Term Care Facilities. I am an infection control professional with responsibility for supporting over 20 long term care facilities in California. Part of my duties include implementing the Federal, State and local regulations as they relate to the prevention and control of infection. This requirement is needed to protect the 1.6 million residents living in long term care facilities from influenza and pneumococcal disease.

1. On page 47764, first paragraph of the second column; please clarify the use of the word Consent. All admissions sign a consent to treat. Written Consent needs to be differentiated from Informed Consent. The Vaccine Information Sheet (VIS) can be given to the resident or designed decision maker and documented in the medical record to fulfill requirement for Informed Consent. Special Written Consent is not required for vaccination. (see www.immunize.org/catg.d/2027law.pdf)

2. If vaccination is refused, please clarify the intent of appropriate education and consultation. Who is qualified to give consultation on immunizations? Can it be a licensed healthcare provider (MD, DO, RN, LPN/LVN, trained person)?

3. Part of a comprehensive immunization strategy must include the influenza vaccination of employees. While the proposed changes acknowledge the importance of staff immunization, these changes fall short by not requiring influenza vaccination of employees. Outbreaks of influenza in long term care facilities have implicated staff through either the introduction or on-going transmission of influenza. The vaccine is about 90% effective in preventing influenza in a young, healthy person, such as a healthcare worker.

As the Proposed Rules in the August 12, 2005 Federal Register point out, the weakness of the current regulation has allow long term care facilities to avoid their responsibility to vaccinate residents against influenza and pneumococcal disease. This weakness is also present in the current requirement 42 CFR 483.65(b)(2) which states that “The facility must prohibit employees with a communicable disease… from direct contact with residents… if the contact will transmit disease.” This requirement is reactive, while the annual employee influenza vaccination requirement would be proactive.

The March 18, 2005 CDC manual titled ‘‘Prevention and Control of 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/longterm- care.pdf). Part I, Section C of that document also recommends a policy with the following:

Statement authorizing the development and use of standing orders or advanced physician prescribed orders, for administering vaccines and monitoring residents after vaccine administration. This should be described in the Facility Policy in the Admission Statement outlining immunizations required for employment and/or statement recommending that employees consider vaccination for influenza or other vaccine-preventable diseases (see Part IV).

The annual administration of influenza vaccination to employees as a condition of employment should be included in the proposed changes. I suggest that all current employees be vaccinated or sign a declination statement by November 15 of each year. This program would continue to be required of all new hire employees until March 31. The employee should be given the opportunity to refuse vaccination, which would then require them to complete education on the dangers of not being vaccinated. If they refuse to be vaccinated, they should then be required to sign a declination statement, similar to the declination statement used for eligible employees who refuse the hepatitis B vaccine (OSHA Blood borne Pathogens). The influenza declination would include a statement like, “I understand that by refusing to be vaccinated against influenza, I pose a risk of serious illness or death to my residents, my co-workers, visitors and my family.” This document would be kept in the employee’s OSHA required Medical Record.

Please consider this additional wording in the final version of this proposed change. I look forward to the final publication and implementation of this rule.

Sincerely,

James Marx, RN, MS, CIC
Broad Street Solutions
PO Box 16557
San Diego, CA 92176
619-656-7887 Voice/Fax

Submitter : **Ms. Karen Steinberg** **Date: 08/30/2005**

Organization : **Ms. Karen Steinberg**

Category : **Long-term Care**

Issue Areas/Comments

GENERAL

GENERAL

I strongly object to the vaccination requirements for long-term care facilities. While patients could opt out, there would be considerable pressure on them to submit to vaccines which might not be safe or appropriate for them. They wouldn't be provided with the reasons to consider not vaccinating, hence, there would be a lack of informed consent.

Submitter : **Eve Lewis** **Date: 08/30/2005**

Organization : **NE HHSS Regulations**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

The Nebraska State Agency supports the proposal to add (n) Influenza and pneumococcal immunization to 483.25 - Quality of Care. We believe that requiring nursing homes to ensure immunization of their residents will provide better care for the elderly and the healthcare workers who care for them.

However, the implementation of this regulation will have an impact on the survey process by increasing the tasks to be completed in order to determine compliance with the new requirement and will increase the amount of time required to complete the survey.

Thank you for the opportunity to provide comment regarding the proposed regulation.

NE HHSS - Regulations & Licensure
Credentialing Division

Submitter : **Date: 08/30/2005**

Organization :

Category : **Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see Microsoft Word attachment

CMS-3198-P-37-Attach-1.DOC

August 29, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244–8010.

Re: CMS–3198–P

Dear Doctor McClellan:

The National Influenza Vaccine Summit is a coalition of over 75 stakeholders, both private and public, in influenza vaccine research, production, distribution, advocacy, and administration, all committed to achieving the Healthy People 2010 goals for influenza vaccine. We support the proposed rule modifying 42CFR Part 83 , Subpart B, by adding paragraph (n) to section 483.25 to require influenza and pneumococcal vaccination in long term care facilities. The proposed modification is well thought out and importantly, does not penalize the facility if the resident or the resident's legal representative refuses immunization or there are medical contraindications. We also believe it wise to require documentation of said refusal but encourage that these details be left up to individual facilities to develop their own protocols and documentation formats.

Finally, it is likely that the long term care community will respond positively to CMS's stated willingness to respond to a potential vaccine shortage by instructing State Survey Agencies not to cite facilities as out-of-compliance with the proposed rule if they were unable to obtain vaccine due to a shortage. However, we believe that this exception is of enough consequence that CMS should consider writing it into the rule. In conclusion, we believe that the proposed rule is a valuable contribution to the improving the health of vulnerable elders and disabled individuals who reside in long term care facilities.

Sincerely,

Raymond Strikas, MD
Litjen (L.J) Tan, PhD

Representing the Executive Committee of the National Influenza Vaccine Summit:

Name
Credentials
Title
Organization
Alfisi, Jennifer

Director of Government Relations
Health Industry Distributors Association (HIDA)
Hannan, Claire

Executive Director, AIM
Association of Immunization Managers (AIM)
Hopkins, Robert
MD, FAAP, FACP
Medical Director, General Internal Medicine Clinic, UAMS College of Medicine
American College of Physicians (ACP)
Kavesh, William
MD, MPH
Immunization
Liaison, Clinical Practices Committee
American Medical Directors Association (AMDA)
Rothholz, Mitchel
RPh, MBA
Vice President, Professional Practice
American Pharmacists Association (APhA)
Stone, Roslyn
MPH
Chief Operating Officer
Corporate Wellness, Incorporated
Tan, Litjen (L.J)
PhD
Director, Infectious Disease, Immunology, and Molecular Medicine
American Medical Association (AMA)
Vassallo, Susan

Director, Corporate Communications
Henry Schein, Inc.
Wexler, Deborah
MD
Executive Director
Immunization Action Coalition (IAC)
Wright, Steven

National Director of Wellness Services
Maxim Health Services
Ariyapadi N. Krishnaraj

Vice President of Marketing

Chiron Vaccines
Coelingh, Kathleen
PhD
Senior Director. Regulatory and Scientific Affairs
MedImmune Vaccines, Inc.
Hosbach, Philip

Vice President, New Products and Immunization Policy
Aventis-Pasteur
Harrison, James
MAPA
Public Health Advisor
Centers for Disease Control and Prevention (CDC), National Immunization Program (NIP), immunization Services Division (ISD), Office of the Director (OD)
Strikas, Raymond
MD
Associate Director for Adult Immunization
Centers for Disease Control & Prevention (CDC), National Immunization Program, Immunization Services Division, Office of the Director

Submitter : **Mrs. Adrienne Rubino** **Date: 08/30/2005**

Organization : **Mrs. Adrienne Rubino**

Category : **Long-term Care**

Issue Areas/Comments

GENERAL

GENERAL

This flu shot has cause more death in nursing homes because these vaccines are not bactera free, especially if it is made in liverpool, England. It was also stated last year that the flu shot to the eldery does not work at all because of their ageing immune system. A definate NO to this law!!!!! Where is our freedmm to run a nursing home and because big business wants more money we are cut off from medicare for the patience. Total blackmale situation!!!!!

Submitter : **Mrs. Kathy Reep** **Date: 08/30/2005**

Organization : **Florida Hospital Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

On behalf of its member hospitals and health systems, many of which operate both hospital-based and freestanding long term care facilities, the Florida Hospital Association appreciates this opportunity to express its support of the proposed rule revising the conditions of participation for long term care facilities, published in the August 15, 2005 Federal Register. Under the proposed rule, 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.

The FHA supports this change as the prevention of influenza and pneumococcal disease is both cost effective and good practice. Simply put, it is the right thing to do!

Submitter : **Dr. David Smith** **Date: 08/30/2005**

Organization : **American Medical Directors Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3198-P-40-Attach-1.PDF

CMS-3198-P-40-Attach-2.PDF

Submitted via: www.cms.hhs.gov/regulations/ecomments

6A national organization of long term care physicians committed to quality care

American Medical Directors Association

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August 30, 2005

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3198–P
P.O. Box 8010
Baltimore, MD 21244–8010

re: File Code CMS-3198-P

Dear Dr. McClellan,

The American Medical Directors Association (AMDA) and the American Geriatrics Society (AGS) are pleased to provide comments on the Proposed Rule for the *Immunization Standard for Long Term Care Facilities*.

AMDA represents more than 7,000 medical directors, attending physicians, and others who practice in nursing homes. AMDA physicians see an average of 100 nursing facility patients per month per member (approximately 8.5 million visits in 2000 or 42 percent of the total number of nursing facility visits that year). AMDA physicians also care for patients in other venues in the long-term care continuum, which includes hospitals, home health care, assisted living settings, hospice and other sites of care for the frail elderly.

Our joint comments on this proposed regulation reflect that experience, as well as the commitment to provide the best quality of care to our patients.

We endorse CMS's Proposed Rule requiring that long term care facilities offer *all* residents immunizations against influenza and pneumococcal disease. This is a valuable initiative that will hopefully save lives and money.

General Comments

With the brief 15-day response time, we are providing specific comments in only two areas: staff immunizations and conditions of participation. If given more time, members of AMDA's Immunization Committee would have liked to complete a joint review of options and have provided comments about the issue of written consent versus informed consent (contained in the first paragraph of the provisions of the Proposed Rule). Our initial concern focuses on whether the issue of written consent might present a barrier to a successful immunization program. We hope you will give stakeholders the time to deliberate on this issue and provide a thoughtful response. AMDA will be discussing the issue at a future meeting of our Immunization Committee and reviewing such articles as "Is Signed Consent for Influenza or Pneumococcal or Polysacchride Vaccination Required" by Kissam, Gifford, et al. However, in light of the time constraint, we propose two suggestions.

One suggestion is that written consent could be obtained from the resident and/or responsible party at admission. This signed consent would not need to be renewed on a yearly basis as the facility staff (usually the RN) would still need to assess each resident yearly to see if there are any health contraindications against receiving the flu vaccination. (The pneumococcal vaccination presumably would be given at time of admission if indicated.) The other suggestion is that written or informed consent not be necessary since CMS is mandating all residents, except those medically contraindicated, be vaccinated. According to the article by Kissam et al, (Arch Intern Med. 2004;164:13-16) Obtaining signed consent prior to administering the vaccines represents and obstacle to achieving the goals of Healthy People 2010. He states that signed

consent is neither legally mandated or nor a guarantee that the resident or proxy has given informed consent.

Specific Comments

II. Provisions of the Proposed Rule; 2nd Paragraph

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.

We believe the Proposed Rule understates the importance of staff immunizations. We propose that long term care facilities be required to offer flu shots to all staff. The Joint Commission on Accreditation of Healthcare Organizations now is entertaining a serious proposal to require that healthcare workers get flu shots. In addition, CMS should strengthen the recommendation that staff be educated as to their role in preventing influenza illness in nursing facilities.

II. Provisions of the Proposed Rule; 1st Paragraph

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.
Subacute-type facilities with short stays may find the Conditions of Participation more difficult, but all hospitals are under increasing pressure to have effective immunization programs (e.g., their pneumococcal immunization data are publicly reported on Hospital Compare). Hopefully the hospital associated skilled nursing facilities will get help in developing their programs.

Respectfully submitted,

David Smith, MD, FAAFP, CMD
President
American Medical Directors Association

David Reuben, MD
President
American Geriatrics Society

Attachment

Submitter : **Dr. Michael Maves** **Date: 08/30/2005**

Organization : **American Medical Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3198-P-41-Attach-1.PDF

residents shortly after admission, tracking vaccination status throughout the year, resourcing vaccination campaigns appropriately, and firmly endorsing such barrier-removing policies as standing orders for residents (see CMS' MedQIC Web site at http://www.medqic.org/dcs/ContentServer?cid=1105558764442&pagename=Medqic%2FContent%2FParentShellTemplate&parentName=StrategyForChange&siteVersion=null&c=MQParents).

We believe that this rule, as currently proposed, would impede rather than increase efforts to improve immunization rates in LTC for the following reasons: 1) it pertains solely to patients in NF, does not consider its impact on the immunization rate of employees and volunteers in NFs or on other LTC priority residents, such as individuals residing in assisted living facilities; 2) it lacks contingency plans for regional or nationwide shortages of influenza vaccination; and 3) the documentation requirements are much more burdensome than CMS describes.

This letter includes general comments followed by specific comments on the different sections of the proposed rule. We hope that CMS will give serious consideration to our comments and not impose unnecessary and unsupported regulations.

GENERAL COMMENTS

Over the years, AHCA has worked in partnership and alone to improve the influenza immunization rate in LTC facilities. In 2001, we were active partners in the Standing Orders Project and we participated in the American Society of Consultant Pharmacists' 100% Immunization Campaign, assisting in the development and dissemination of a resource manual. In 2004, we worked closely with Quality Partners of Rhode Island in the development of an immunization toolkit. During the 2004-2005 flu season, we worked with the CDC, CMS and Aventis Pasteur to help direct the limited supply of influenza vaccine to NFs, assisted living facilities and intermediate care facilities for persons with mental retardation and developmental disabilities. Throughout the years, we have participated in the National Influenza Vaccine Summit that is coordinated by the American Medical Association. This past year, AHCA participated in the "NICK the Flu Project" and assisted CMS with locating a NF in which to videotape training. These examples of our activities, along with our regular dissemination of information to our members on immunization, illustrate our strong support of actions to improve the influenza and pneumococcal immunization rates in all LTC facilities.

Although we strongly support efforts to improve influenza and pneumococcal immunization rates in NFs, this proposed rule would impede rather than increase efforts to improve immunization rates in LTC and negatively impact influenza immunization in other priority settings. AHCA disagrees with CMS' statement that this rule would facilitate the delivery of appropriate vaccinations to residents in LTC facilities. As we explain in the following bullets and in our comments under "BACKGROUND—Sections A – E," we find little evidence to support CMS' statement:

* The CMS Web site on Medicare preventive services that contains information on the Influenza/Pneumonia Immunization Campaign 1996 vaccination rates and 1997 vaccination rates clearly notes

limitations in the data. CMS states that the data presented are based on submitted claims and that providers who do not bill Medicare are not represented in the data. CMS acknowledges that the extent of the data limitation problem and magnitude of bias are unknown.
* Information captured on nursing home immunization rates derived from the Resident Census and Conditions of Residents (Form 672) has limitations in validly representing influenza and pneumococcal immunization rates. Resident Census Form 672 represents current resident status. Form 672, F144 – Received influenza immunization, requires manual coding and requests the total number of residents known to have received the influenza immunization within the last 12 months. Reported data only include those residents in the facility at the time of survey who receive the vaccination at the facility and does not reflect immunizations that are offered but refused nor does it reflect when the vaccine was contraindicated. The form also does not capture residents who received influenza vaccinations for the most current season prior to being admitted to a NF.
* Form 672, F145, Received pneumococcal vaccine, requests the number of residents known to have received the pneumococcal vaccine. As stated immediately above, the entered data only represents those residents in the NF at the time of survey, does not reflect individuals who refused vaccines or for whom the vaccine is contraindicated and those individuals receiving the vaccine prior to their NF stay.

Before assumptions are made about immunization rates in NFs to determine if regulation is needed, much more accurate data are needed. While the proposed rule is well meaning, without accurate information supporting the need for regulatory scrutiny, the requirements are merely a regulatory burden without a substantiated goal. AHCA urges CMS to delay any decisions relating to requiring immunization until information from the new Section W, Supplemental MDS Items can be analyzed.

In the absence of accurate data, we question why CMS has turned NF immunization rates into a survey issue rather than seeking constructive solutions to this data limitation issue. Currently, hospitals and other providers rarely share immunization information with NFs. Instead of focusing resources on surveying immunization, we urge the Federal government to expand its efforts and resources to establish health information technology that would track individuals' immunizations over time and across provider settings.

Finally, we are concerned that the language in the proposed regulation is inconsistent when defining the requirements for immunizations. Under the Summary Section (page 47759) the goal of the proposed rule is to require LTC facilities to offer each resident immunization against influenza and pneumonia. In the very next sentence, the proposed rule states that each facility would be required to ensure that each resident receives the immunizations. This is a critical distinction yet the proposed rule interchanges the action verbiage as if their meaning is the same throughout the Federal Register notice. We suggest that if CMS chooses to go forward with this proposed regulation, it first clarify and include more explicit language in the proposed rule.

BACKGROUND—Sections A – E

AHCA supports ACIP's recommendation that all residents of LTC facilities should be assessed for their needs for pneumococcal polysaccharide vaccine (PPV) and that they receive the vaccine if eligible. We

agree that influenza vaccination is the cornerstone for the control and treatment of influenza. AHCA has worked tirelessly with CDC, CMS, Quality Improvement Organizations (QIOs) and other stakeholders to increase the rate of influenza vaccination of both patients and employees in both NFs and assisted living facilities.

However, we believe that this section of the proposed rule unfairly and inaccurately characterizes the extent to which immunizations are offered and provided in NFs. For the following reasons, AHCA does not agree with claims in this section of the proposed rule that there is valid evidence to support this proposed rule to mandate NFs to offer each patient immunization against influenza annually, as well as lifetime immunization against pneumococcal disease:

* The research cited to support the need for influenza vaccine and PPV for NF patients are a mix of NF studies, Medicare Current Beneficiary Surveys and National Center for Health Statistics studies on general population immunization rates and thus lack sufficient evidence to support the premise that immunization in NFs need to be mandated by a condition of participation.
* Rather than relying on 1998 and 1999 data on general information and statistics of influenza morbidity and mortality rates to try to show NF immunization rates, it would be far more accurate to look at the number of doses paid by Medicare Part B for vaccine does in nursing homes.
* In citing the 1999 National Nursing Home Survey that reports on the previous year's vaccination rates, CMS ignores the importance of standing orders programs that were later instituted and the increase in reimbursement rates for influenza vaccination. CMS acknowledges (p. 47760), To date, we do not have data on the specific immunization rates of nursing facility residents since the publication of this rule [rule that removed the physician order requirement for influenza and pneumococcal vaccinations].
* CMS cites the Healthy People 2010 goal of immunizing 90% of all persons over 65 years of age annually for influenza and lifetime immunization for pneumococcal pneumonia. The majority of the population over 65 will not reside in NFs yet CMS makes no effort to measure the immunization rate for this population. In calculating the immunization rate in NFs, CMS considers only the rate of vaccination received and fails to consider NF patients who were vaccinated prior to admission, for whom the vaccine is contraindicated or those who were offered but refused it.
* The proposed rule cites a CMS/CDC report, Respiratory Disease in Nursing Homes, which indicates that pneumococcal vaccination may be associated with reduction in mortality and a 12% to 28% reduction in all-cause hospitalizations in NF residents. The evidence justifying the need for PPV fails to identify the number of patients admitted to NFs with an admitting diagnosis of pneumonia. In the 1999 issue of Facts and Trends: The Nursing Facility Sourcebook produced by AHCA, ICD-9-CM code 486, Pneumonia, organism unspecified was listed as one of the top 15 nursing home Medicare admission codes. The provision of PPV by NFs will reduce the incidents of pneumococcal disease acquired by patients residing in facilities, but does nothing to reduce the rate of NF admissions resulting from pneumonia. The proposed rules claims, (page 47763) that it …has the potential to reduce overall healthcare costs by reducing the need for the treatment of influenza and pneumococcal diseases and their complications. This claim overstates the impact on overall healthcare cost savings in the absence of consideration to the number of nursing homes patients whose reason for admission relates to influenza and pneumonia.

AHCA also questions the logic of this background section of the proposed rule, which cites the ACIP

priorities as a rationale for mandating vaccine in NFs even though the ACIP primary target group, Persons at increased risk for influenza-related complications (for example, those aged >65 years and persons of any age with certain chronic medical conditions) include people living outside NFs. The proposed rule notes, 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. Yet CMS makes no effort to consider the impact of this proposed rule on residents of other LTC facilities. Specific problems to consider include:

* Though assisted living facilities fall into the CDC priority category, there was confusion last year during the influenza vaccine shortage, with some states hesitant to direct the limited supply of influenza vaccine to assisted living facilities. The proposed rule likely would further that confusion.
* CMS estimates that the new requirements would increase the number of NF patients receiving flu shots by about 320,000 annually, but CMS does not relate the impact of this increased demand on high-risk assisted living residents.
* Under the New Freedom Initiative, the federal government encourages states to transition patients from NFs to home- and community- based settings. This rule does not consider how the increased demand in NFs will impact the availability of flu vaccine for those individuals who transition out of NFs prior to flu season.

Finally, clarification is needed in statements in this section and interspersed in other sections that do not routinely identify the residents' right to refuse as an option for not providing immunizations. For example, the proposed rule states (page 47761) that it is vital to residents in nursing homes that they are offered immunizations and if not medically contraindicated, and that facilities ensure that the residents receive the immunizations at the appropriate time to prevent the spread of the influenza virus. A statement acknowledging the right to refuse should be included in such statements.

BACKGROUND SECTION F, VACCINE SHORTAGES

The proposed rule states that "nursing home residents" were deemed a priority during the 2004 influenza vaccine shortage. In fact, "long term care residents" were deemed the priority and included in this group are assisted living residents. As stated in the section above, AHCA has serious concerns about the impact of this proposed rule on assisted living residents and other priority individuals should there be a vaccine shortage.

CDC has reported national vaccine shortages for the past 5 years. The shortage during 2004-2005 season brought forth increased awareness of influenza vaccination. This awareness and the aging of the population combined with this proposed rule increases the likelihood of future national shortages. Yet there is no discussion in the proposed rule of contingencies for delay or shortage of vaccine. If CMS mandates immunization, it must provide direction on criteria-based vaccination contingency plans. In addition, the rule states that CMS could exercise its enforcement discretion in a true vaccine shortage. AHCA would expect that in a true vaccine shortage as declared by the CDC, CMS would unequivocally instruct the state survey agencies not to cite facilities as out-of-compliance. We ask CMS to make this clearer should it proceed with this proposed rule. Finally, the proposed rule does not address the

potential that there could be local or regional shortages or delays in supplies. CMS also should address this possibility in its proposed rule.

PROVISIONS OF THE PROPOSED RULE

AHCA has several concerns relating to the provisions of the proposed rule, as follows:
* One provision of the proposed rule indicates that the resident or legal guardian must receive appropriate education and consultation regarding the benefits of influenza and pneumococcal immunizations. Informed consent would require that residents or legal representatives receive information of benefit and risks prior to vaccination. The proposed provision only indicates education on the benefits. This recommendation is not consistent with best practice. AHCA recommends that appropriate education and consultation be defined appropriately.
* Section 42 CFR 483.65 requires that all NFs establish and maintain an infection control program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of disease and infection. The intent of the regulation is to assure that NFs have programs effective for investigating, controlling and preventing infections. Furthermore, state surveyors have the enforcement capability under F441 to assure that influenza and pneumococcal vaccinations are given. Appendix PP to the State Operation Manual directs surveyors to cite a deficiency under F441 if the facility does not have measures to address prevention of infections. The immunizations for influenza and pneumococcal pneumonia are both listed as programs that should be in place. Thus, it is not clear why a new regulation under 42 CFR 483.25 in needed.
* In speculating on the purpose of placing the proposed regulation under 483.25 rather than 483.65, concern arises that if documentation deficiencies are deemed widespread by the state surveyor, the nursing facility can be found to be in a position of substandard care and subject to termination of the nurse aide training program.
* “Legal representative” should be defined and the proposed rule should clarify whether a family member or responsible party is considered a legal representative or if a representative having durable power of attorney is required. In defining legal representative, the existence or absence of states laws need to be considered. What constitutes legal representative in one state may not be the same in another. The proposed rule should identify where and the extent of documentation needed to record the response from the legal representative (example: name of legal representative, date and place where vaccination administered, is a certificate of vaccination needed, etc.).
* The proposed rule states (page 47764), It is important for facilities to remember that residents have the right to refuse immunizations. However, educating residents and family members regarding the benefits of receiving immunization generally results in consent. This is an unsupported conclusion with no reference cited.
* The Exception under Section (2) (iv) is not clear. What are the guidelines for the assessment, who qualifies as a “practitioner,” and in what form is the “practitioner recommendation” documented?
* There is no provision for a situation in which the influenza vaccination strain does not match the influenza strain. In such an instance, vaccinating patients and risking side effects may not be best policy.
* The proposed rule includes an expectation (page 47763) that NFs would obtain previous immunization history on each resident, yet other providers are under no requirement to furnish this information to the NF. If other health care entities, such as hospitals and physician offices, were expected to obtain this

information and send it to NFs with the admitting paperwork, we could better understand this requirement. It is inappropriate to place the burden of compiling this information solely on NFs who often do not receive this information from other health entities and cannot rely on obtaining the information from the patient. According to the June 2005 OSCAR data, 46.32% of NF patients have dementia, 2.83% have mental retardation and a significant portion of the NF population has other mental and behavioral disorders that can impact the accuracy of information provided by the patient. NFs cannot rely on family for accurate information since they most likely would not have access to a complete vaccination record if one exists, or have accurate-enough information that can be used in making care decisions.

COLLECTION OF INFORMATION REQUIREMENTS

AHCA believes that CMS has significantly understated the burden and unfunded fiscal impact of the proposed rule.

* Per Section III, page 47765, the estimated 100 residents per facility used to calculate nurse time for policy and protocol development, documenting a resident's immunization status, immunization cost and cost savings is actually based on the average bed count rather than the actual number of residents. Reports from providers indicate that they admit about 10.5 residents per month. Over the influenza season, this comes out to be an additional 63 residents per facility. In considering the turnover, the adjusted documentation burden per facility is 5 minutes per resident X 163 residents per facility X 16,139 facilities = 219,221 hours per year, not 134,482. The total cost is 219,221 hours X $23.70 (average salary for a registered nurse) = $5,195,538, not $3,187,460.

* Initial costs would include much more than CMS' estimate of 5 hours of a registered nurse's time. The proposed rule neglects to consider the time for the medical director and other members of the pharmacy committee and the infection control committee to participate in the development and approval of facility-specific protocols, policies and procedures. Once developed, all staff will need to be educated and monitoring systems that provide for quality improvement measurements will need to be established and followed.

* Ongoing costs are much higher than the 5 minutes of a registered nurse's time that is estimated in the proposed rule. Additional time considerations include the following:

o Approximately 15 to 120 minutes per new resident for the staff to research the resident's past immunization status. The new Section W of the MDS is better than the current incomplete methods for determining immunization efforts, but does little to help providers learn about an individual's immunization history when he/she is admitted into the facility and at a time when this information is needed. In using the MDS as a vehicle for collecting immunization data, NFs still have to obtain immunization information from the medical record which may or may not contain immunization history or from many individuals with cognitive impairment or with memory problems. Hospitals routinely fail to provide this important information upon transfer to the nursing facility.

o Additional time needed to contact and obtain permission from legal representatives or families in those cases when a patient does not make medical treatment decisions.

o Additional recordkeeping time, which would include time spent reviewing patients' medical records to determine if giving the vaccine is contraindicated.

o For those individuals who decline to accept the vaccines, at least 20 to 30 minutes of nurses' time would be required to provide and document efforts to educate and consult with both residents and their families.

WAIVER OF THE 60-DAY COMMENT PERIOD

The 60-day comment period can be waived with good cause if a 60-day comment period is impracticable, unnecessary, or contrary to the public interest. CMS notes that by shortening the 60-day comment period to 15 days, it will have time to finalize the provisions before October 1, 2005. CMS asserts that the 60-day comment period is detrimental to the health of NF patients and by allowing a 15-day comment period, a rule can be implemented in time to ensure that vaccinations can be administered for the 2005-2006 influenza season and infection rates can be contained.

In fact, implementing this proposed rule during the 2005-2006 influenza season is more likely to wreck havoc and confusion since providers were required to pre-book vaccine orders for the upcoming influenza season no later than this past July. Many pharmacies that supply influenza vaccines to nursing facilities requested that orders for the number of doses for the upcoming season be placed as early as April 2005. Sanofi Pasteur closed their pre-booking after only one day as the demand was so great. Considering the timing, the rule should have been published for comment in the early spring to accommodate pre-booking requirements.

Though there is little mention in this rule of immunizing health care workers, many NFs include their workers in their pre-booked orders. As the order is based on previous history of the number of NF patients who accept the vaccine, NFs would have to shift vaccine from their employees to their patients to meet the proposed rule's new mandate this year. This would be a terrible step backward when one considers the difficulties NFs have experienced in convincing health care workers to be vaccinated against influenza.

To conclude, the proposed rule, if implemented, would be punitive to NFs that already are successfully offering influenza immunization and PPV and would unfairly characterize the extent to which immunizations are offered and provided in NFs. We emphatically urge CMS to continue initiatives that encourage voluntary implementation of ACIP recommendations for a successful vaccination program, including combined publicity and education for health care workers and other potential vaccine recipients, and use of reminder/recall systems, and similar approaches instead of requiring the utilization of resources on survey and documentation. AHCA remains committed to working with CMS and other entities in these voluntary efforts. Finally, we stress the importance of directing government resources to ensure full and timely supply of vaccine to all priority individuals and again, offer our active participation in such efforts.

AHCA appreciates opportunities to work collaboratively with CMS and other government officials to improve influenza and pneumococcal immunization rates in LTC facilities. We look forward to continuing to work with CMS and others on voluntary initiatives that will improve the influenza and pneumococcal immunization rate of residents in all LTC facilities and their employees, as well.

Sincerely,

Jim Smith
Sr. Vice President for Advocacy

6

Submitter : **Thomas Clark** **Date: 08/30/2005**

Organization : **American Society of Consultant Pharmacists**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-3198-P-42-Attach-1.DOC

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow “Attach File” button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Ms. Robin Frank** **Date: 08/30/2005**

Organization : **Healthcare Association of New York State**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3198-P-43-Attach-1.DOC

August 30, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3198-P
P.O. Box 8010
Baltimore, Maryland 21244-8010

Re: Medicare and Medicaid Programs; Condition of Participation: Immunization Standard for Long Term Care Facilities

Dear Dr. McClellan:

On behalf of the American Medical Association (AMA) and its physician and medical student members, we are pleased to offer our comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule to require long-term care facilities serving Medicare and Medicaid patients to provide immunizations against influenza and pneumonia.

The American Medical Association (AMA) has long advocated that patients at risk of pneumococcal or influenza infections receive the appropriate vaccination. Certainly, residents of long-term care facilities are among the most vulnerable to morbidity and mortality due to influenza and pneumococcal infections.

The AMA thus applauds this carefully thought out proposal to require influenza and pneumococcal vaccination in long term care facilities. Significantly, this proposed change would not penalize the facility if the resident or the resident's legal representative refuses immunization, or if there are medical contraindications. Although it is preferable that documentation be obtained of vaccine refusal, such administrative details should rightly be left to individual facilities to develop their own protocols and documentation formats.

The AMA is delighted to see CMS' commitment to improving influenza and pneumococcal immunization rates, especially among high-risk populations. We urge that CMS also continue to appropriately recognize the physician work and practice expense involved in the administration of influenza and pneumococcal vaccines in the payment rates for this service, as well as maintain adequate reimbursement for the influenza vaccine.

It is also critical that the costs of the increased utilization of immunization services attributable to this rule be recognized in the law and regulation factor of the Sustainable Growth Rate (SGR). Physicians already face a steep pay cut next year and cumulative cuts of 26% from 2006-2011. Physicians should not have to be concerned that they will contribute to future Medicare pay cuts each time they provide these highly effective services. As Medicare is transformed into a more prevention-oriented program, increased utilization of covered preventive services must be recognized in the SGR.

Finally, it is likely that the long-term care community will respond positively to CMS' stated willingness to respond to a potential vaccine shortage by instructing State Survey Agencies not to cite facilities as being out-of-compliance with the proposed rule in the event they are unable to obtain vaccine due to such a shortage. Indeed, this exception is of enough consequence that CMS should consider writing it into the rule itself.

In conclusion, the AMA believes that the proposed rule is a valuable contribution to improving the health of vulnerable seniors and disabled individuals who reside in long-term care facilities.

Sincerely,

Michael D. Maves, MD, MBA

Submitter : Janice Zalen **Date:** 08/30/2005

Organization : American Health Care Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter.

CMS-3198-P-44-Attach-1.DOC

residents shortly after admission, tracking vaccination status throughout the year, resourcing vaccination campaigns appropriately, and firmly endorsing such barrier-removing policies as standing orders for residents (see CMS' MedQIC Web site at http://www.medqic.org/dcs/ContentServer?cid=1105558764442&pagename=Medqic%2FContent%2FParentShellTemplate&parentName=StrategyForChange&siteVersion=null&c=MQParents).

We believe that this rule, as currently proposed, would impede rather than increase efforts to improve immunization rates in LTC for the following reasons: 1) it pertains solely to patients in NF, does not consider its impact on the immunization rate of employees and volunteers in NFs or on other LTC priority residents, such as individuals residing in assisted living facilities; 2) it lacks contingency plans for regional or nationwide shortages of influenza vaccination; and 3) the documentation requirements are much more burdensome than CMS describes.

This letter includes general comments followed by specific comments on the different sections of the proposed rule. We hope that CMS will give serious consideration to our comments and not impose unnecessary and unsupported regulations.

GENERAL COMMENTS

Over the years, AHCA has worked in partnership and alone to improve the influenza immunization rate in LTC facilities. In 2001, we were active partners in the Standing Orders Project and we participated in the American Society of Consultant Pharmacists' 100% Immunization Campaign, assisting in the development and dissemination of a resource manual. In 2004, we worked closely with Quality Partners of Rhode Island in the development of an immunization toolkit. During the 2004-2005 flu season, we worked with the CDC, CMS and Aventis Pasteur to help direct the limited supply of influenza vaccine to NFs, assisted living facilities and intermediate care facilities for persons with mental retardation and developmental disabilities. Throughout the years, we have participated in the National Influenza Vaccine Summit that is coordinated by the American Medical Association. This past year, AHCA participated in the "NICK the Flu Project" and assisted CMS with locating a NF in which to videotape training. These examples of our activities, along with our regular dissemination of information to our members on immunization, illustrate our strong support of actions to improve the influenza and pneumococcal immunization rates in all LTC facilities.

Although we strongly support efforts to improve influenza and pneumococcal immunization rates in NFs, this proposed rule would impede rather than increase efforts to improve immunization rates in LTC and negatively impact influenza immunization in other priority settings. AHCA disagrees with CMS' statement that this rule would facilitate the delivery of appropriate vaccinations to residents in LTC facilities. As we explain in the following bullets and in our comments under "BACKGROUND—Sections A – E," we find little evidence to support CMS' statement:

* The CMS Web site on Medicare preventive services that contains information on the Influenza/Pneumonia Immunization Campaign 1996 vaccination rates and 1997 vaccination rates clearly notes

limitations in the data. CMS states that the data presented are based on submitted claims and that providers who do not bill Medicare are not represented in the data. CMS acknowledges that the extent of the data limitation problem and magnitude of bias are unknown.
* Information captured on nursing home immunization rates derived from the Resident Census and Conditions of Residents (Form 672) has limitations in validly representing influenza and pneumococcal immunization rates. Resident Census Form 672 represents current resident status. Form 672, F144 – Received influenza immunization, requires manual coding and requests the total number of residents known to have received the influenza immunization within the last 12 months. Reported data only include those residents in the facility at the time of survey who receive the vaccination at the facility and does not reflect immunizations that are offered but refused nor does it reflect when the vaccine was contraindicated. The form also does not capture residents who received influenza vaccinations for the most current season prior to being admitted to a NF.
* Form 672, F145, Received pneumococcal vaccine, requests the number of residents known to have received the pneumococcal vaccine. As stated immediately above, the entered data only represents those residents in the NF at the time of survey, does not reflect individuals who refused vaccines or for whom the vaccine is contraindicated and those individuals receiving the vaccine prior to their NF stay.

Before assumptions are made about immunization rates in NFs to determine if regulation is needed, much more accurate data are needed. While the proposed rule is well meaning, without accurate information supporting the need for regulatory scrutiny, the requirements are merely a regulatory burden without a substantiated goal. AHCA urges CMS to delay any decisions relating to requiring immunization until information from the new Section W, Supplemental MDS Items can be analyzed.

In the absence of accurate data, we question why CMS has turned NF immunization rates into a survey issue rather than seeking constructive solutions to this data limitation issue. Currently, hospitals and other providers rarely share immunization information with NFs. Instead of focusing resources on surveying immunization, we urge the Federal government to expand its efforts and resources to establish health information technology that would track individuals' immunizations over time and across provider settings.

Finally, we are concerned that the language in the proposed regulation is inconsistent when defining the requirements for immunizations. Under the Summary Section (page 47759) the goal of the proposed rule is to require LTC facilities to offer each resident immunization against influenza and pneumonia. In the very next sentence, the proposed rule states that each facility would be required to ensure that each resident receives the immunizations. This is a critical distinction yet the proposed rule interchanges the action verbiage as if their meaning is the same throughout the Federal Register notice. We suggest that if CMS chooses to go forward with this proposed regulation, it first clarify and include more explicit language in the proposed rule.

BACKGROUND—Sections A – E

AHCA supports ACIP's recommendation that all residents of LTC facilities should be assessed for their needs for pneumococcal polysaccharide vaccine (PPV) and that they receive the vaccine if eligible. We

agree that influenza vaccination is the cornerstone for the control and treatment of influenza. AHCA has worked tirelessly with CDC, CMS, Quality Improvement Organizations (QIOs) and other stakeholders to increase the rate of influenza vaccination of both patients and employees in both NFs and assisted living facilities.

However, we believe that this section of the proposed rule unfairly and inaccurately characterizes the extent to which immunizations are offered and provided in NFs. For the following reasons, AHCA does not agree with claims in this section of the proposed rule that there is valid evidence to support this proposed rule to mandate NFs to offer each patient immunization against influenza annually, as well as lifetime immunization against pneumococcal disease:

* The research cited to support the need for influenza vaccine and PPV for NF patients are a mix of NF studies, Medicare Current Beneficiary Surveys and National Center for Health Statistics studies on general population immunization rates and thus lack sufficient evidence to support the premise that immunization in NFs need to be mandated by a condition of participation.
* Rather than relying on 1998 and 1999 data on general information and statistics of influenza morbidity and mortality rates to try to show NF immunization rates, it would be far more accurate to look at the number of doses paid by Medicare Part B for vaccine does in nursing homes.
* In citing the 1999 National Nursing Home Survey that reports on the previous year's vaccination rates, CMS ignores the importance of standing orders programs that were later instituted and the increase in reimbursement rates for influenza vaccination. CMS acknowledges (p. 47760), To date, we do not have data on the specific immunization rates of nursing facility residents since the publication of this rule [rule that removed the physician order requirement for influenza and pneumococcal vaccinations].
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o For those individuals who decline to accept the vaccines, at least 20 to 30 minutes of nurses' time would be required to provide and document efforts to educate and consult with both residents and their families.

WAIVER OF THE 60-DAY COMMENT PERIOD

The 60-day comment period can be waived with good cause if a 60-day comment period is impracticable, unnecessary, or contrary to the public interest. CMS notes that by shortening the 60-day comment period to 15 days, it will have time to finalize the provisions before October 1, 2005. CMS asserts that the 60-day comment period is detrimental to the health of NF patients and by allowing a 15-day comment period, a rule can be implemented in time to ensure that vaccinations can be administered for the 2005-2006 influenza season and infection rates can be contained.

In fact, implementing this proposed rule during the 2005-2006 influenza season is more likely to wreck havoc and confusion since providers were required to pre-book vaccine orders for the upcoming influenza season no later than this past July. Many pharmacies that supply influenza vaccines to nursing facilities requested that orders for the number of doses for the upcoming season be placed as early as April 2005. Sanofi Pasteur closed their pre-booking after only one day as the demand was so great. Considering the timing, the rule should have been published for comment in the early spring to accommodate pre-booking requirements.

Though there is little mention in this rule of immunizing health care workers, many NFs include their workers in their pre-booked orders. As the order is based on previous history of the number of NF patients who accept the vaccine, NFs would have to shift vaccine from their employees to their patients to meet the proposed rule's new mandate this year. This would be a terrible step backward when one considers the difficulties NFs have experienced in convincing health care workers to be vaccinated against influenza.

To conclude, the proposed rule, if implemented, would be punitive to NFs that already are successfully offering influenza immunization and PPV and would unfairly characterize the extent to which immunizations are offered and provided in NFs. We emphatically urge CMS to continue initiatives that encourage voluntary implementation of ACIP recommendations for a successful vaccination program, including combined publicity and education for health care workers and other potential vaccine recipients, and use of reminder/recall systems, and similar approaches instead of requiring the utilization of resources on survey and documentation. AHCA remains committed to working with CMS and other entities in these voluntary efforts. Finally, we stress the importance of directing government resources to ensure full and timely supply of vaccine to all priority individuals and again, offer our active participation in such efforts.

AHCA appreciates opportunities to work collaboratively with CMS and other government officials to improve influenza and pneumococcal immunization rates in LTC facilities. We look forward to continuing to work with CMS and others on voluntary initiatives that will improve the influenza and pneumococcal immunization rate of residents in all LTC facilities and their employees, as well.

Sincerely,

Jim Smith
Sr. Vice President for Advocacy

6

Submitter : **Dr. Dennis Cuddy** **Date: 08/30/2005**

Organization : **Dr. Dennis Cuddy**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

I am glad that your proposed rules say it is "vital that facilities secure the consent of their residents or legal representative for vaccination." However, it must be clear that the consent is WRITTEN, otherwise you have no proof the consent was actually given. Moreover, the consent must be "informed." By this, I mean it is not enough that residents be told "the benefits of influenza immunization," but also the RISKS. Every time my father was vaccinated for influenza, he got the flu and became very sick. The last time, he DIED. Sincerely, Dr. Dennis Cuddy

Submitter : **Dr. Thomas Lawrence** **Date: 08/30/2005**

Organization : **Main Line Health/Jefferson Health System**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Proposed regulation CMS Immunization Standard for Long-Term Care Facilities
483.25 Quality of care
Paragraph (n)

This comment is offered by a physician who is a Geriatric Medicine specialist, and who has extensive experience as a nursing facility Medical Director in 12 nursing facilities in Pennsylvania (currently Medical Director of 6 nursing facilities).

The proposed regulation dictates a time interval for requiring influenza vaccination to be October 1 through March 31. It is a well established nursing home infection control practice that the Medical Director determines the optimal time for beginning the annual Fall influenza vaccination program in a facility. It is also well established that it is undesireable to begin vaccination too early in the season for frail, elderly, nursing home residents due to the concern of waning immunity late in the influenza season and loss of protection. The ideal time for initiating the facility's program is usually linked to reports of whether there have been early cases of influenza identified in the community and the region. The Medical Director is instrumental in determining when the vaccination program should begin within their facility. Although it is not detrimental for any one nursing home resident to receive vaccination earlier than the optimal start date, it would be improper for the vaccination start date to be arbitrarily determined by a Federal nursing home regulation as October 1.

I recommend that the language of the final regulation be changed to allow for the nursing facility Medical Director to determine the optimal time to begin the vaccination program in the fall. For nursing facility residents, the optimal date for starting influenza vaccination is most often closer to November 1 than to October 1. The CDC guidelines on this issue support this position. The proposed regulation as written suggests that October 1st is a required starting date for a facility's influenza vaccination program; this needs to be clarified and corrected.

Submitter : **Mrs. Brenda Taylor** **Date: 08/30/2005**

Organization : **Mrs. Brenda Taylor**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

Section VI. The assumptions list rates for administration and vaccine. Our facility is receiving only $7.05 for administration and $7.05 for vaccine. If all facilities have to meet the same standard, why is reimbursement also not standard. Our reimbursement has not changed in years.

Submitter : **Ms. Sue Sebazco** **Date: 08/30/2005**

Organization : **Association for Professionals in Infection Control**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3198-P-48-Attach-1.DOC

August 29, 2005

Mark McClellan, MD, PhD
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3198-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8010

Dear Dr. McClellan:

On behalf of the Association for Professionals in Infection Control and Epidemiology (APIC) we thank you for the opportunity to offer comment on the issue of influenza and pneumococcal disease immunization in long-term care facilities.

Studies indicate that approximately 90 percent of influenza fatalities each year are elderly citizens. Elderly citizens, particularly those housed in long-term care facilities, are among the type of patients that we consider being at a high risk for contracting influenza and pneumonia. As such, APIC supports your agency on this proposed rule that would require beneficiaries living in long-term care facilities to be annually vaccinated against influenza and pneumonia. We believe this is a valuable step in the fight against the spread of unnecessary illness among one of our most vulnerable populations.

APIC is a multi-disciplinary voluntary international health organization with more than 10,000 members whose primary responsibility is infection prevention and control and epidemiology. APIC's mission is to improve health and promote patient and employee safety by reducing risks of infection and other adverse outcomes. APIC advances this goal through education, research, collaboration, practice and credentialing.

Again, we thank you for allowing us to weigh in on this important proposal and encourage you to contact Denise Graham, Senior Director of Public Policy at dgraham@apic.org should you require the expertise of our membership.

Sincerely,

Sue Sebazco, RN, BS, CIC
2005 APIC President

Submitter : **Mr. Andrew Schlafly** **Date: 08/30/2005**

Organization : **Association of American Physicians and Surgeons**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3198-P-49-Attach-1.DOC

Re: Immunization Standard for Long Term Care Facilities, CMS-3198-P

These comments are submitted on behalf of the Association of American Physicians & Surgeons, Inc. ("AAPS"), a nonprofit group of thousands of physicians that was founded in 1943.

AAPS objects to the lack of protection for elderly patients or residents who decline vaccination. The regulation should specifically prohibit any retaliation by CMS or a CMS-funded facility against anyone for refusing a vaccination.

AAPS also objects to the lack of consideration of the harm that will be caused by adverse reactions to the vaccines. The estimate of savings fails to consider the substantial injuries and medical costs that inevitably occur from mass vaccination. Moreover, the proposal lacks any means for tracking that important data in evaluating how well the program is working.

AAPS further objects to requiring the patients or residents to consider receiving vaccination when the workers at the facilities are not also subjected to vaccination. Why must vaccination be imposed on residents but not the workers? The flu and other illnesses are more likely to be introduced and spread by workers than by the elderly residents themselves. The double-standard is troubling and raises questions about the validity of the program.

AAPS further objects to the estimate of $5 million per life saved in a nursing home. While all life is sacred, placing $5 million per life saved on someone likely to die in a few weeks or months is exaggerated and unjustified. The savings are grossly inflated through use of this estimate.

The estimate in the proposed regulation for the documentation time required for both immunizations is too low, further inflating the benefits of the proposal. More than five minutes is required to complete all the documentation required for two immunizations. Review of a medical contraindication to vaccination could easily take an hour in documenting, for example, in order to prevent an erroneous vaccination. When all the reporting is considered along with the maintenance of records, the actual time spent (and cost) could be many times that estimated.

Finally, AAPS objects to the waiver of the 60-day period, replaced with an unreasonably short period allowed for commenting on these proposed regulations. It takes more than 15 days in August, when many are away on vacation, to digest, consider and submit comments on such an important proposal.

Thank you for your consideration of these comments.

Andrew Schlafly
AAPS General Counsel

Submitter : **Ms. Heather Olson** **Date: 08/30/2005**

Organization : **Iowa Hospital Association**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3198-P-50-Attach-1.PDF

CMS-3198-P-50-Attach-2.PDF

August 30, 2005

The Honorable Dr. Mark McClellan
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS -3198-P, P.O. Box 8010
Baltimore, MD 21244-8010

Ref: CMS 3198-P Medicare and Medicaid Programs: Condition of Participation: Immunization Standard for Long Term Care Facilities: Proposed Rule (69 *Federal Register 47759*.)

Dear Dr. McClellan,

On behalf of the 46 Iowa hospital-based distinct part skilled nursing facilities (SNFs) and nursing facilities (NFs), IHA is pleased to take this opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) proposed rule for the Conditions of Participation (CoP): Immunization Standard for Long Term Care (LTC) Facilities published in the August 15, 2005 *Federal Register*.

Requirements for Long Term Care Facilities

In this proposed rule, CMS proposes to 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 to reduce the mobidity and mortality rates of these contagious and infectious diseases. IHA has long been a supporter that the Medicare program be a purchaser of value, and to reward high quality, efficient health care providers. A focus on improving quality of care will ultimately improve both the well being of Medicare beneficiaries and the fiscal integrity of the Medicare program. **IHA supports the proposal that would require the administration of both vaccinations if appropriate and needed to improve the quality of care provided to Medicare beneficiaries**.

IHA urges CMS to provide prompt and detailed instruction on how LTC providers are to bill and be reimbursed for such services given the urgency to enact this rule prior to the beginning the 2005-2006 year's flu season. The final rule fails to provide information on how LTC providers would bill and receive payment from the Medicare program for the supplies and administration of the vaccinations. Currently, outpatient hospital departments may submit a roster bill for patients receiving the influenza vaccination. It is unclear how CMS intends LTC units to maintain the documentation in the medical record, and receive payment for the vaccine, particularly in SNF units that are reimbursed on using a case-mix classification system referred to as Resource Utilization Groups (RUGs). Iowa hospital-based SNFs have a long history of negative Medicare margins. With

the recent refinement of the case-mix classification system, and elimination of add-on payments, IHA urges CMS to provide adequate reimbursement to cover the cost of obtaining the vaccinations and for administering them.

IHA also requests that CMS provide clarification in the final rule that this proposed change to the Conditions of Participation does not apply to skilled nursing facility services provided in hospital swing-beds.

Thank you for your review and consideration of these comments. If you have questions, please contact me at the Iowa Hospital Association at 515/288-1955.

Sincerely,

Heather Olson
Director, Finance Policy

cc: Iowa Congressional Delegation
IHA Board of Trustees
Iowa hospitals
CMS Kansas City Regional Office

Submitter : **Mr. Brian Abraham** **Date: 08/30/2005**

Organization : **MedImmune**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-3198-P-51-Attach-1.DOC

August 30, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3198-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

VIA ELECTRONIC SUBMISSION

Re: Immunization Standard for Long Term Care Facilities (CMS-3198-P)

Dear Administrator McClellan:

MedImmune is pleased to submit our comments on the Centers for Medicare and Medicaid's (CMS's) proposed rule to increase immunization rates in Medicare and Medicaid participating long term care (LTC) facilities. Dedicated to advancing science and medicine to help people live better lives, the company is focused on the areas of infectious diseases, cancer, and inflammatory diseases. As the manufacturer of the live, attenuated (intranasal) influenza vaccine, FluMist®, we are very concerned that vulnerable populations continue to be exposed unnecessarily to the influenza virus. We applaud your efforts to help ensure that Medicare and Medicaid beneficiaries who are residents of LTC facilities be protected from both the influenza and pneumococcal viruses. In that vein, we offer comments that we hope will further CMS's efforts to improve the status of the residents of these facilities.

About FluMist

FluMist is indicated for active immunization for the prevention of disease caused by influenza A and B viruses in healthy children and adolescents, 5 to 17 years of age, and healthy adults, 18 to 49 years of age. It has been shown to be safe and effective in clinical studies of both children and adults. More than two million doses of FluMist have been distributed over the last two flu seasons. In some flu seasons, a new, unpredicted flu strain may emerge that does not match any of the flu strains contained in the vaccines. This vaccine mismatch makes it harder for any vaccine to provide protection. However, in children, FluMist has demonstrated 87% protection against influenza both in a season when there was a good vaccine match (1996-1997), and when there was vaccine mismatch (1997-1998).

There are risks associated with all vaccines, including FluMist. As with any vaccine, FluMist does not protect 100% of individuals vaccinated. In placebo-controlled clinical trials, the most common solicited adverse events in the indicated population (n=2,762) included runny nose/nasal congestion, headache, cough, sore throat, tiredness/weakness, irritability, decreased activity and muscle aches.

FluMist is contraindicated in persons with hypersensitivity to any component of the vaccine, including

eggs; in children and adolescents receiving aspirin therapy or aspirin-containing therapy; in individuals with a history of Guillain-Barré syndrome; and in individuals with known or suspected immune deficiency. The safety and efficacy of FluMist have not been established in pregnant women or for patients with chronic underlying medical conditions, including asthma or reactive airways disease; the vaccine should not be administered to these patients. See Prescribing Information for indications and usage, dosage and administration, and safety information. A copy of the prescribing information for FluMist is attached (electronically) to this comment letter.

Although this vaccine is not indicated for the high-risk population aged 65 or older, nor for the highest-risk individuals, we believe that FluMist has its place in the LTC environment, and that the final rule would be CMS's opportunity to suggest additional ways to protect vulnerable populations, including Medicare beneficiaries older than 65 and Medicaid beneficiaries in higher-risk categories.

Provisions of the Proposed Rule

In accordance with the statement that CMS is not proposing to require LTC facilities to develop protocols or documentation for this activity1, we encourage you to emphasize and encourage facilities to minimize exposure of the influenza virus unnecessarily to residents. CMS acknowledges that one of the ways to do this is to encourage staff members of the facilities to obtain immunization (against both influenza and pneumococcal disease).2 In addition, the Advisory Committee on Immunization Practices (ACIP) emphasizes in its 2005-2006 influenza immunization recommendations, that all health care workers receive immunization against influenza in order to help prevent the higher-risk populations they care for from unwarranted exposure to the influenza virus.3 The ACIP goes on to say that during times when there is a shortage or scarcity of the inactivated flu vaccine, FluMist should be "especially encouraged" for health care workers in good health between ages 18 and 49, because its use "might considerably increase the availability of inactivated vaccine for persons in groups at high risk"(such as those residing in LTC facilities).4 Finally, ACIP has stated that FluMist has been demonstrated to reduce the prevalence of medically attended acute respiratory illness in personal contacts of vaccine recipients.5

ACIP also has stated that household contacts (including children) are at risk to transmit the influenza virus6. CMS also cites earlier ACIP recommendations and CDC statistics supporting this notion.7 Thus, vaccinating these individuals could help prevent the spread of the disease to a vulnerable or high-risk individual, including a related health care worker or contact in a LTC facility.

Because of these recommendations, as well as CMS's stated intent to protect the vulnerable populations residing in LTC facilities, we request that CMS state in the final rule more strongly that it encourages LTC facilities to offer immunization programs to its health care workers, with all forms of influenza vaccine available, and especially FluMist if there is a shortage of inactivated vaccine.

We also encourage CMS to communicate to LTC facilities that they inform families of residents about obtaining influenza immunizations in order to reduce the transmission of the disease from outside contacts to the residents of these facilities. Again, FluMist should be an option to healthy contacts, aged

5 to 49.

For questions concerning this letter or other matters before CMS, please contact me at (301) 398-4626 or abrahamb@medimmune.com. Thank you again for your consideration.

Sincerely yours,
Brian C. Abraham
Associate Director, Reimbursement

Enclosure

1 70 FR 47763.
2 70 FR 47764.
3 CDC. Prevention and Control of Influenza, Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2005;54 (RR08): at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5408a1.htm.
4 Ibid.
5 Ibid.
6 Ibid.
7 70 Fed Reg 47760.
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Submitter : **Ms. Andrea Ludington** **Date: 08/30/2005**

Organization : **Beverly Enterprises, Inc.**

Category : **Long-term Care**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-3198-P-52-Attach-1.DOC

August 30, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 309-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201
Attn: File Code CMS-3844-P

Re: Comments on Medicare and Medicaid Programs; Condition of Participation: Immunization Standard for Long Term Care Facilities, Federal Register Volume 70, No. 156, August 15, 2005, CMS Reference #CMS-3844-P

Dear Dr. McClellan:

Beverly Enterprises, Inc. (BEI) provides long term care services to patients in multiple states. We are pleased to offer comments on CMS' proposed changes to 42 CFR 483.

Initially, BEI would express our support of CMS' efforts to ensure the provision of influenza and pneumococcal vaccines to nursing facility patients. BEI has historically provided these vaccines to our patients, and applauds CMS for elevating the provision of such vaccines to a Condition of Participation for the Medicare and Medicaid programs. However, we would urge caution in adopting regulations in this area, to ensure that both patient and facility responsibilities in this area are carefully described. To that end, we would offer the following specific comments to the proposed rule.

In the section titled "II. Provisions of the Proposed Rule", beginning on page 47763 of the Federal Register notice, CMS indicates that specific protocols and documentation will not be included in the proposed rule. BEI urges you to reconsider this provision and to at the very least describe within the rules a standardized format for obtaining the required documentation. Such standardization will not only serve to protect the facility from potential liability, but will in addition serve as a guide to surveyors in determining compliance with these requirements.

Finally, we would express our concern with the section F, also found at page 47763 of the proposed rule, which acknowledges the potential for vaccine shortages, and provides that in the event of a "true vaccine shortage as declared by CDC", survey agencies will be instructed not to cite facilities for non-compliance. We appreciate your inclusion of the very real potential for vaccine shortages, as faced by health care providers nationwide during last year's flu season. However, we would ask for additional clarification to the language "true vaccine shortage as declared by CDC" and how CMS would invoke its discretion to exercise this instruction to state survey agencies. We would suggest instead that CMS

policy be declared as, "In a CDC declared shortage of the vaccine, the facility may not be cited unless they do not have an immunization protocol and program in place".

BEI applauds your efforts and leadership in this area, and appreciates your attention to our concerns.

Sincerely,
Andrea Ludington
Senior Vice-President, Professional Services

1

Submitter : **Rebecca Rex** **Date:** **08/30/2005**

Organization : **Rebecca Rex**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow “Attach File” button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Date: 08/30/2005**

Organization :

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-3198-P-54-Attach-1.RTF

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow “Attach File” button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Rebecca Rex **Date:** 08/30/2005

Organization : Rebecca Rex

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Regarding CMS-3198-P

The rules proposing standing orders for flu and pneumococcal vaccine use in long term care facilities as a condition of participation in the Medicare and Medicaid programs will likely lead to gaps in treatment and care of some individuals. Currently mandatory immunization requirements for children are leading a number of doctors to refuse to care for families who do not follow the mandated schedule. These families have the right to exemptions from immunization, as well as the right to refuse medical treatment. Yet they are left without medical homes. The doctors have expressed concerns about being penalized for deviating from performance standards.

Though the proposed rules allow for a resident to refuse the offered vaccines, the fact that administering these vaccines will be a factor in a facility's ability to participate in the Medicare/Medicaid programs will cause some residents to be denied care based on that refusal. There must be at least penalities for facilities that threaten to no longer house a resident for refusal.

Rebecca Rex