



October 9, 2009

Assistant Secretary for Health
Office of Public Health and Science
Office of Population Affairs
Washington DC 20201

TO: Regional Health Administrators, Regions I-X

FROM: Acting Director, Office of Population Affairs

SUBJECT: OPA Program Instruction Series, OPA 09-02:
Provision of 2009 H1N1 Vaccination in Title X Family Planning Projects

As you may be aware, on July 24, 2009, Secretary of Health and Human Services Kathleen Sebelius renewed the April 26, 2009, declaration by then Acting Secretary Charles E. Johnson that a public health emergency exists nationwide involving novel influenza A (H1N1) virus (which will be referred to throughout this Program Instruction as 2009 H1N1). The purpose of this Program Instruction is to provide guidance to Title X Family Planning service grantees regarding the provision of the 2009 H1N1 vaccination.

CDC's Advisory Committee on Immunization Practices (ACIP) has determined that certain groups of the population are at relatively higher risk, and should receive the 2009 H1N1 vaccine as soon as it becomes available. These target groups include pregnant women, people who live with or care for children younger than 6 months of age, healthcare and emergency medical services personnel, persons between the ages of 6 months and 24 years old, and people ages 25 through 64 year of age who are at higher risk for 2009 H1N1 because of chronic health disorders or compromised immune systems. Vaccination efforts are designed to help reduce the impact and spread of 2009 H1N1.

Title X providers are encouraged, but not required, to make the 2009 H1N1 vaccine available to Title X healthcare personnel as well as to clients within Title X clinics, and may choose to provide the vaccine either as part of the Title X project, or outside of the Title X project. When the 2009 H1N1 vaccine is provided as part of the Title X project, all Title X regulations must be followed (e.g., confidentiality, schedule of discounts, nondiscrimination, etc.). In addition, grantees should be aware of other State and/or Federal requirements regarding provision of the vaccine.

Title X providers that provide the 2009 H1N1 vaccine, but not as part of the Title X project, must account for those services and the corresponding charges (e.g., staff time, etc.) separate and distinct from the Title X project.

Healthcare personnel within the Title X service system are at high risk for exposure to 2009 H1N1, and providing them with the vaccine will help to prevent the spread of H1N1 to uninfected co-workers and clinic patients. Also, among the target groups for the vaccine are pregnant women and persons between the ages of 6 months and 24 years. As documented on the

most recent Family Planning Annual Report (2007 FPAR), more than half (55%) of clients who receive services in Title X-funded family planning clinics are 24 years of age or younger. Pregnant women are a priority group for receiving the 2009 H1N1 vaccine, and although prenatal services are not within the scope of Title X, pregnancy testing and early pregnancy education and counseling are among the most commonly provided services in family planning clinics. Since it may be several weeks before the pregnant woman is seen for a first prenatal visit, pregnancy testing and diagnosis at a family planning clinic is an important opportunity to provide the 2009 H1N1 vaccine before a pregnant woman may be exposed to the virus.

In addition, Title X regulations at 42 CFR Part 59, Subpart A, § 59.5 (b)(2) (“What requirements must be met by a family planning project?”) stipulate that projects must, unless the Secretary determines that the project has established good cause for its omission, “Provide for social services related to family planning, including counseling, referral to and from other social and medical services agencies, and *any ancillary services which may be necessary to facilitate clinic attendance*” (emphasis added). Provision of the 2009 H1N1 vaccine by Title X clinics may encourage more individuals to come to a clinic, where they could be provided with family planning services as well as the vaccine. However, note that only clients that meet the FPAR definition of a “family planning user” and receive a family planning service in addition to the 2009 H1N1 vaccine may be counted on the FPAR.

Grantees that are interested in providing the vaccine should visit the following CDC websites: http://www.cdc.gov/H1N1flu/vaccination/clinicians_qa.htm and <http://www.cdc.gov/h1n1flu/vaccination/statelocal/>. As explained in the CDC websites above, the Federal Government is the only source for the vaccine, and it is being allocated to states based on population size. The Federal Government is purchasing vaccine and supplies (syringes, alcohol swabs, sharps containers, and vaccine record cards) and distributing these at no cost to healthcare providers who make agreements with State and local public health authorities to provide the H1N1 vaccine. States are responsible for identifying providers who will participate in administration of the H1N1 vaccine, and State and local health departments are responsible for directing the flow of vaccine to providers within States. A number of States have already established registries for providers to request 2009 H1N1 vaccine allocations, and Family Planning service grantees are encouraged to work closely with their States to make their needs known and register with their State public health authorities to receive the vaccine. For more information, grantees should contact the State public health department website or the CDC 2009 H1N1 website at <http://www.cdc.gov/H1N1flu/>.

While the vaccine is free, providers are able to charge a fee for the administration of the vaccine, which is an allowable cost within the Title X program. Medicaid and the Children’s Health Insurance Program (CHIP) will pay the administration fee for those clients that are eligible

under these programs. For additional information, grantees should be directed to <http://www.cms.hhs.gov/smdl/downloads/SHO092409.pdf>.

Grantees that are interested in providing the 2009 H1N1 vaccine should be aware of the Public Readiness and Emergency Preparedness (PREP) Act which provides broad liability protections, including protections associated with the administration of covered countermeasures, such as the 2009 H1N1 vaccine. Liability protections were put in place to ensure that an adequate supply of countermeasures was produced and made available in the U.S. by vaccine manufacturers. The PREP Act also provides a mechanism to compensate eligible individuals for covered injuries from a covered countermeasure. For an overview of these protections, see www.hhs.gov/disasters/emergency/manmadedisasters/bioterrorism/medication-vaccine-qa.html.

For purposes of consistency, please direct all grantee questions regarding provision of the 2009 H1N1 vaccine to Central OPA.



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cc: Regional Program Consultants for Family Planning