



Center for Medicaid and State Operations

SHO # 09-011

September 24, 2009

Dear State Health Official:

As you may be aware, on July 24, 2009, Secretary Kathleen Sebelius renewed the declaration that a public health emergency exists nationwide involving novel influenza A (2009 H1N1), which will be referred throughout this document as 2009 H1N1. This declaration, first initiated on April 26, 2009, was made under the authority of section 319 of the Public Health Service Act. While this Secretarial declaration has no direct impact on the Medicaid program or the Children's Health Insurance Program (CHIP), the declaration supports a number of Federal emergency response activities and underscores the importance of ensuring that States are reviewing the operation and management of their Medicaid and CHIP programs to ensure that beneficiaries receive health care services related to 2009 H1N1 influenza effectively, efficiently and in the most appropriate settings. This letter provides guidance to States regarding these matters. This letter covers the following topics:

- I. Vaccination Funding and Vaccine Administration
- II. Presumptive Eligibility
- III. Beneficiaries with Suspected or Confirmed 2009 H1N1 Influenza
- IV. Provisions for Beneficiaries Receiving Services Through Managed Care Entities
- V. People Receiving Home and Community-Based Waiver Services and State Plan Services
- VI. Health Care Workforce Planning
- VII. Administrative Funding for Activities Related to Education and Outreach
- VIII. Emergency Medical Services Under Section 1903(v) of the Social Security Act

In addition to this guidance, the Centers for Medicare & Medicaid Services (CMS) will be available to provide ongoing technical assistance to States and will be offering an expedited State plan amendment (SPA) review/approval process when States request necessary modification(s) to their State plans related to 2009 H1N1. For up-to-date information about Federal emergency response and related activities during the period of this 2009 H1N1 influenza public health emergency, States, Medicaid and CHIP providers are directed to the Federal Government's Web sites at www.flu.gov and www.cdc.gov/h1n1flu/guidance.

In general, the coverage and other issues discussed below apply to all full-benefit Medicaid beneficiaries (including those whose benefits are funded through CHIP/Medicaid expansion programs). These are also applicable to beneficiaries in separate CHIP programs and the letter

identifies circumstances in which beneficiaries in separate CHIP programs are treated differently than Medicaid beneficiaries.

I. Vaccination Funding and Vaccine Administration

The 2009 H1N1 vaccine is currently in clinical trials. The two Federal Web sites referenced above, www.flu.gov and www.cdc.gov/h1n1flu/guidance will have the most up-to-date information about the vaccine.

(A) High-priority Populations

The Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC) have identified the following target groups to receive the 2009 H1N1 vaccine when it becomes available in mid-October 2009:

- **Pregnant women** because they are at higher risk of complications and can potentially provide protection to infants younger than 6 months of age who cannot be vaccinated;
- **Household contacts and caregivers for children younger than 6 months of age** because younger infants are at higher risk of influenza-related complications and cannot be vaccinated. Vaccination of those in close contact with infants less than 6 months old might help protect infants by “cocooning” them from the virus;
- **Healthcare and emergency medical services personnel** because they are at very high risk of exposure to the new H1N1 virus and because infections among healthcare workers can be a potential source of infection for vulnerable patients. Also, increased absenteeism in this population could reduce healthcare system capacity;
- **Children from 6 months through 18 years of age** because we have seen many cases of novel 2009 H1N1 influenza in children and they are in close contact with each other in school and day care settings, which increases the likelihood of disease spread;
- **Young adults 19 through 24 years of age** because we have seen many cases of novel 2009 H1N1 influenza in these healthy young adults and they often live, work, and study in close proximity, and they are a frequently mobile population; and,
- **Persons aged 25 through 64 years who have health conditions associated with higher risk of medical complications from influenza.**

(B) Vaccine Funding and Vaccine Administration

The vaccine itself will be purchased by the Federal Government. Information about vaccine distribution can be found on the CDC Web site at http://www.cdc.gov/H1N1flu/vaccination/statelocal/centralized_distribution_qa.htm.

While the vaccine will be free, providers will be allowed to charge a fee for the administration of the vaccine. Medicaid and CHIP programs will be responsible for covering the administration fee for eligible populations. States are encouraged to review the vaccine administration fees outside of the Vaccines for Children (VFC) program to ensure they are adequate to provide broad access to the 2009 H1N1 vaccine.

- While the purchase and distribution of the 2009 H1N1 vaccine will be outside of the purview of the Vaccine for Children program, States will still be required to reimburse the administration fee for the 2009 H1N1 vaccine for individuals under the age of 21 as part of the Medicaid Early and Periodic Screening, Diagnostic and Treatment program (EPSDT). Under the Medicaid EPSDT benefit, individuals under age 21 are entitled to vaccine coverage as recommended by ACIP, with payment for the vaccine and vaccine administration as specified in the State plan. In addition, States are required to inform all individuals under the age of 21 who have been determined to be eligible for Medicaid of the availability of EPSDT services including the need for age-appropriate immunizations against vaccine preventable diseases. Informing should also include a discussion of the benefits of preventive services and how to obtain those services. States may target “at risk” groups for specific informing (e.g., pregnant woman).
- For children covered in a separate CHIP program, coverage of ACIP-recommended vaccine administration is a requirement of well-baby and well-child care.
- For adults in the Medicaid program, 2009 H1N1 vaccine administration is a covered service when furnished by a participating provider under a “mandatory” section 1905(a) Medicaid benefit. Since hospital, physician and federally qualified health center/rural health clinic (FQHC/RHC) services are mandatory Medicaid benefits, 2009 H1N1 vaccine administration would be a covered service when provided by these participating providers. States should carefully review their State plans, and if necessary, submit State plan amendments to remove barriers to non-provider participation, and allow coverage of adult 2009 H1N1 vaccine administration by providers in settings that are considered “optional” Medicaid benefits (e.g., freestanding clinics, independent licensed non-physician practitioners). States should also review their State plan payment methodologies to ensure appropriate payment for vaccine administration. An expedited SPA review process is available.

The Department of Health and Human Services is providing more than \$1 billion to States for vaccine administration. States should ensure that Medicaid and other Federal funding sources are appropriately coordinated to prevent duplicate payments.

States should encourage Medicaid and CHIP enrollees to present eligibility information to vaccination and treatment sites to facilitate appropriate billing.

(C) Roster Billing for 2009 H1N1 Vaccine

Roster billing can substantially lessen the administrative burden on providers by allowing them to submit one claim identifying all eligible Medicaid and CHIP beneficiaries that receive the 2009 H1N1 vaccine on a given day. While we recognize that this could place additional administrative burdens and costs on the States if they have not previously designed their system to process roster billings, we encourage States to examine their ability to modify their systems and processes to accommodate roster billing for 2009 H1N1 vaccines, and any future mass immunization programs. The costs for implementing system changes and operations would qualify for the enhanced rate associated with the operation of the Medicaid Management Information System.

(D) 2009 H1N1 Vaccine HIPAA-Compliant Codes

CPT 90465-90474 are codes for vaccine administration. For coding (identifying) the 2009 H1N1 vaccine, States may wish to use the current CPT code 90663, which is a generic code for pandemic influenza virus vaccine.

(E) Providing Vaccinations in Additional Settings

To the extent that States have not done so already, States are encouraged to expand coverage for vaccine administration to a range of providers and settings, including non-traditional care sites, in order to efficiently and effectively provide vaccinations to large numbers of Medicaid and CHIP beneficiaries. These could include walk-in clinics at retail stores/outlets/pharmacies and school-based health centers/clinics. Other ways for States to consider expanding their capacity to cover/provide mass vaccinations would be to establish clinics under physician direction at schools. Note that Federal requirements pertaining to clinic services at 42 CFR 440.90 require that services be provided “under the direction of a physician.” Physician direction can be met, in the case of vaccinations, through standing orders provided by the physician or other forms/mechanisms of indirect physician direction/supervision where the physician is not necessarily on-site. The physician must, however, assume professional responsibility for the service/vaccinations provided by those under his/her direction and be readily available for direction/consultation.

Depending on the State’s current State Medicaid or CHIP plan, a SPA may be required to effectuate some of these options to expand provision of and access to 2009 H1N1 vaccinations. CMS will assure that such SPAs are acted upon promptly and expeditiously.

II. Presumptive Eligibility

Many of the individuals who are in priority categories for receiving 2009 H1N1 vaccinations are uninsured children and pregnant women who are eligible for Medicaid or CHIP but not enrolled. States have the option to provide Medicaid and CHIP services during a presumptive eligibility period. Presumptive eligibility provides immediate coverage to an individual while a formal eligibility determination is being made. Because of the time required to apply and to complete a determination for a child or pregnant woman, presumptive eligibility ensures that care is not

delayed while the individual is going through the eligibility determination process. In order to assure prompt diagnosis and treatment of 2009 H1N1 influenza cases, CMS encourages States to amend their Medicaid or CHIP State plans to provide a period of presumptive eligibility for children and pregnant women. States may not limit the populations of children and pregnant women to whom this option is applied (e.g., only to individuals with suspected or confirmed 2009 H1N1 influenza), except to define the income and ages of children (not to exceed age 19) to whom this option is applied. States may, however, limit the categories of entities it will permit to determine presumptive eligibility.

Under a presumptive eligibility option, qualified providers or other entities designated by the State determine presumptive eligibility based on preliminary information about the individual's family income. Payment to providers and Federal financial participation to the State is assured for services provided during the presumptive eligibility period. Federal requirements at sections 1902(a) and 1920 of the Act specify that States may provide ambulatory prenatal care during a presumptive eligibility period for pregnant women.

Under CHIP, requirements for States to offer CHIP coverage during a presumptive eligibility period for pregnant women can be found at section 2112(c) (as added by the Children's Health Insurance Program Reauthorization Act of 2009). States that offer coverage to children during a presumptive eligibility period are required to offer full Medicaid or CHIP coverage to children under age 19. Requirements for children are specified at sections 1902(a) and 1920A of the Act for Medicaid and at section 2107(e)(1)(D) for CHIP. The Medicaid implementing regulations can be found at 42 CFR 435.1100-1102 and the CHIP requirements related to presumptive eligibility are at 42 CFR 457.355. States with questions about implementing the option for presumptive eligibility in their Medicaid and/or CHIP program may contact CMS for technical assistance.

III. Beneficiaries with Suspected or Confirmed 2009 H1N1 Influenza

(A) Services

Full-benefit Medicaid and CHIP beneficiaries (adults and children) who are symptomatic with suspected or confirmed 2009 H1N1 influenza are entitled to be covered for medically necessary evaluation and services, including diagnostic testing, treatment and emergency care. These services are covered in a number of ambulatory and other settings that States are required to cover as part of the Medicaid and CHIP benefit packages. For Medicaid, these mandatory services include laboratory, hospital, physician, and FQHC/RHC services. For separate CHIP programs, services are determined by the health benefits coverage option that the State has elected. In both programs, mandatory treatment settings would include emergency room or hospital inpatient settings when appropriate for severe symptoms and complications of 2009 H1N1 influenza (e.g., for pneumonia and serious/life threatening conditions related to 2009 H1N1).

Under EPSDT services, Medicaid children under age 21 are entitled to coverage for any medically necessary diagnostic and treatment service that the State could elect in its approved State Medicaid plan, even if the State has not so elected for other Medicaid

beneficiaries. This would include services provided in additional settings that may not be available to adults under the State plan. Sections (E) and (F) below discuss how States can assure that services are available in alternative care settings.

(B) Standards of Care/Medical Necessity

During the period of this 2009 H1N1 influenza public health emergency, States, Medicaid and CHIP providers, including physicians and hospitals, are directed to the Federal Government's Web sites at www.flu.gov and www.cdc.gov/h1n1flu/guidance for the most up-to-date information to assist them in making medical necessity determinations and in providing services consistent with a professional level of care. States, Medicaid and CHIP providers are directed to these Web sites since they contain relevant, current information and standards of care for providers (and others) pertaining to 2009 H1N1 influenza.

(C) Cost Sharing for Covered Services

Copayments may serve as a deterrent to seeking timely care. Sections 1916(a)(2) and 1916A(b)(3)(B) of the Act, and 42 CFR 447.53(b) specifically exclude certain services from payment of a deductible, cost sharing or similar charge. These services include those provided to children under 18 years, pregnant women and emergency services. For beneficiaries in separate CHIP programs, under section 2103(e) of the Act, States may not impose cost sharing for children or pregnant women for preventive services, such as well-baby and well-child care which, as described in 2103(c), includes age appropriate immunizations such as 2009 H1N1.

(D) Prior Authorization for Drugs

Since the prompt use of antiviral drugs is generally medically necessary to be effective, CMS urges States not to require prior authorization for antiviral medications or other medications necessary to treat 2009 H1N1 influenza.

Where these drugs are prior authorized, the law requires that there must be a system in place to provide a response to a prior authorization request within 24 hours of the request, and the State must provide the dispensing of at least a 72-hour supply of a covered outpatient drug in an emergency situation as defined by the Secretary. The CDC recommends that a full 5-day treatment course of antivirals be prescribed and dispensed immediately for suspected 2009 H1N1 cases for those patients who are severely ill (hospitalized) and those patients who are ill with influenza-like illness and who are at the high-risk for influenza related complications among high-risk populations or with serious illness.

(E) Providers

To ensure access to care, States may consider reaching out to new providers to participate in the Medicaid program. In order to furnish and bill for services provided to Medicaid and CHIP beneficiaries, providers must enroll in the Medicaid and/or CHIP program.

This is done through the execution of an agreement between the State and the provider. Federal Medicaid regulations at 42 CFR Part 431 describes basic Federal requirements which must be met in such an agreement between the State and its providers. However, States are given broad discretion to include/impose additional requirements on providers in order to enroll in the program. Sometimes these additional requirements are quite lengthy and processing provider applications takes a long time. Therefore, we encourage States to consider streamlining provider applications to ensure that providers can provide 2009 H1N1-related services and can enroll promptly.

(F) Care Sites

To address the threat of the 2009 H1N1 influenza virus and ensure that the health care delivery system is appropriate to meet beneficiary needs, CMS encourages State Medicaid agencies to not only work with public health departments and other entities coordinating plans, but also to consider their options for expanding the sites where Medicaid and CHIP beneficiaries who are symptomatic and require 2009 H1N1 influenza-related services can receive care on an outpatient, ambulatory care basis. Medicaid and CHIP-funded care for eligible individuals with mild to moderate symptoms of 2009 H1N1 flu is available at clinics, physician offices, and FQHCs/RHCs. Such care could also be provided at alternate sites, as long as Federal and State requirements are met.

One of the goals of expanding capacity for providing appropriate ambulatory care/services is to divert individuals, including Medicaid and CHIP beneficiaries, who might otherwise utilize the emergency room, to more appropriate ambulatory settings. To this end, we encourage State Medicaid and CHIP agencies to work with State public health agencies, survey agencies, and providers, including hospitals, to notify/inform the general public and in particular Medicaid and CHIP beneficiaries that appropriate ambulatory care for the treatment of mild to moderate 2009 H1N1 flu symptoms is available and to identify where they might receive that care. Again, depending on the State's current State Medicaid or CHIP plan, a SPA may be required to effectuate some of these options to expand provision of and access to appropriate ambulatory care for 2009 H1N1 influenza-related symptoms.

(G) HIPAA-Compliant Codes for Diagnosis and Treatment of 2009 H1N1

HIPAA-compliant codes are used by providers and payers (including Medicaid and CHIP) to claim and reimburse for covered services. Effective October 1, 2009, a new ICD-9 diagnosis code for H1N1 influenza virus will be established to identify/code patients with suspected or laboratory confirmed 2009 H1N1 influenza. This code will enable providers and payers to identify, track, claim, and reimburse for covered services provided to persons who will/could be covered under title XIX.

IV. Provisions for Beneficiaries Receiving Services Through Managed Care Entities

To the extent that symptoms of suspected or confirmed 2009 H1N1 influenza are sufficiently severe that a prudent layperson might reasonably expect that the absence of immediate treatment

could result in imminent harm to health, managed care entities may not impose prior authorization or referral requirements prior to the assessment, diagnosis and treatment of Medicaid or CHIP beneficiaries presenting with such symptoms. In cases in which the prudent layperson test is not met, Medicaid and CHIP beneficiaries with flu-like symptoms may seek these services from their primary care provider or obtain any necessary referrals from their managed care plan. The Medicaid and CHIP programs should inform all managed care entities in the State of these policies.

V. People Receiving Home and Community-Based Waiver Services and State Plan Services

In the case of a 2009 H1N1 pandemic, continuity and quality of care for people with disabilities and older people with chronic diseases could be seriously impacted. An outbreak could result in a workforce disruption and could require sudden changes in both the types and location of services. States will be expected to take advantage of existing program flexibilities and respond quickly to changing health care needs and ensure provision of quality services.

States have existing flexibility to ensure continuity of services to people currently served under the section 1915(c) waiver program and State plan who require acute care. Under the 1915(c) waiver program, States can “hold” the waiver slot so that a waiver participant who has a short-term hospital or institutional stay can return to the waiver and receive needed community services – for which Medicaid will reimburse the Federal share (as long as the person still maintains Medicaid financial eligibility). Under the State plan, if a Medicaid beneficiary receiving home health care needs to go into a hospital, nursing facility, etc., then home health services may resume upon discharge, provided the beneficiary still meets the State’s medical necessity criteria for the receipt of home health care.

States also have existing flexibility to respond to sudden changes in need for services. For example, if a caregiver becomes ill and unable to provide supports, States have flexibility under both the 1915(c) and State plan programs to ensure availability of supports. For people already enrolled in the 1915(c) Home and Community-Based Services (HCBS) waiver program, States have the authority and flexibility (and a statutory responsibility) to adjust the waiver participant’s plan of care to respond to changing situations in the participant’s life that may require additional services. Any services covered under the approved waiver and authorized by the State are eligible for Federal Medical Assistance Percentage (FMAP). If the State determines that additional services, not already authorized in the approved waiver, are needed, the State may request an amendment to the waiver to add additional services or to serve additional persons. CMS is developing mechanisms through its Web-based waiver application to further expedite the processing of emergency requests from the waiver programs, in the event of a 2009 H1N1 pandemic.

For people receiving services under the Medicaid State plan, if a primary caregiver for a beneficiary is ill and unable to provide care, CMS expects that the provider agency would have an “emergency” plan in place to continue to furnish the services needed by the beneficiary. The “emergency” plan must be communicated to the beneficiary in advance of an emergency and may include use of an online worker registry or replacement staff from the agency. We would

expect the State to determine whether all the provider agencies furnishing services have an emergency plan in place and that it has been communicated to the beneficiary and any representative. In addition, it should be noted that the regulation governing section 1915(j) of the Social Security Act (the self-directed personal assistance services State plan option at 42 CFR 441.464(d)(2)(xiii) and 42 CFR 441.468(a)(4), includes a requirement that a beneficiary has a “back-up” plan in the event a service provider is unable to furnish a needed service and that the plan is made a part of the participant’s service plan. Finally, the regulation governing section 1915(j) also includes a requirement for a risk assessment of each potential risk to the participant and the risk management plan that will mitigate any identified risks not assumed by the participant.

VI. Healthcare Workforce Planning

Healthcare providers, including inpatient facilities, medical offices, clinics, home health agencies and others will play a crucial role in the event of an H1N1 pandemic this fall. Planning is critical, and CMS urges States to work with other state agencies to encourage healthcare providers to plan for workforce protection and business continuity.

Preparation checklists, toolkits, and guidelines that will assist healthcare providers and service organizations in planning for a pandemic outbreak can be found at <http://www.flu.gov/plan/healthcare/index.html>. CMS encourages States to include this information in communication to providers about 2009 H1N1.

VII. Administrative Funding for Activities Related to Education and Outreach

States will continue to have the use of Medicaid and CHIP administrative match for beneficiary and provider education and outreach. CMS encourages States to ensure that Medicaid and CHIP beneficiaries and providers are aware of the availability of the 2009 H1N1 vaccine, understand where beneficiaries may go to receive services, the procedures for receiving those services and contacts for obtaining additional information. Outreach should be aided by Centers for Disease Control and Prevention funding awarded to States through Public Health Emergency Response Program. This funding was intended to provide financial resources for implementing a mass vaccination campaign at the State, local, tribal, and territorial levels.

VIII. Emergency Medical Services Under Section 1903(v) of the Social Security Act

Individuals who are entitled only to Medicaid coverage of emergency medical services under section 1903(v) include those who meet all other Medicaid eligibility requirements such as State residency, income, categorical status, but are undocumented or lawfully residing in the U.S. but subject to the “5-year waiting period.” Emergency medical services related to H1N1 influenza are available to these individuals consistent with section 1903(v).

IX. Coordination with Other Federal Resources and Programs

States should ensure that their Medicaid and CHIP plans for the 2009 H1N1 preparation and response activities are consistent and coordinate with other Federal funds such as the Public

Health Emergency Preparedness (PHEP) and Public Health Emergency Response (PHER) cooperative agreements from CDC, and the Hospital Preparedness Program (HPP) from the Assistant Secretary for Preparedness and Response (ASPR).

In conclusion, CMS understands that States are already working on these and many other 2009 H1N1-related issues, and we look forward to partnering with you to ensure all eligible beneficiaries have access to timely care. We hope this letter is a helpful beginning. If you have any questions, please contact Ms. Krista Drobac at (202) 205-3067 or Krista.Drobac@cms.hhs.gov.

Sincerely,

/s/

Cindy Mann
Director

cc:

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