requests. Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Samia Nasr, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5370, Silver Spring, MD 20993–0002, 301–796–3409.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Guidance to Pharmacies on Advance Compounding of Tamiflu Oral Suspension to Provide for Multiple Prescriptions.'' The increasing prevalence of H1N1 infection and resultant increase in demand for Tamiflu for Oral Suspension has caused supply difficulties and spot shortages of the commercially manufactured Tamiflu for Oral Suspension product (12 milligrams (mg)/milliliter (mL)) throughout the country. Because of these shortages, compounding of Tamiflu Oral Suspension (15 mg/mL), as described in the FDA-approved labeling, can ensure that patients who have difficulty swallowing tablets have access to Tamiflu Oral Suspension when the commercially manufactured Tamiflu for Oral Suspension is unavailable.

This guidance describes the conditions in which FDA will not object to certain compounding of Tamiflu Oral Suspension (using Tamiflu capsules) in advance of receiving prescriptions. In circumstances where there is an actual shortage of commercially manufactured Tamiflu for Oral Suspension, FDA will not object if pharmacies compound oral suspension from Tamiflu capsules in advance of receiving prescriptions, if the amount compounded is commensurate with the number of valid prescriptions that the pharmacy can reasonably anticipate receiving within the next 24 hours.

In addition, the guidance provides detailed, step-by-step information for the preparation of pharmacy-compounded Tamiflu Oral Suspension (final concentration 15 mg/ml) from Tamiflu capsules in quantities that are based on patient weight. Information on proper storage and a dosing chart for pharmacy-compounded Tamiflu Oral Suspension are also provided.

This guidance is being issued as a Level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). It is being implemented immediately without prior public comment because of the shortage of the commercially manufactured Tamiflu for Oral Suspension and the potential hazard to the public health. However, the agency welcomes comments on the guidance and, if comments are submitted, the agency will review them and revise the guidance if appropriate. The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm188629.htm*.

Dated: December 23, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–30750 Filed 12–28–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[CMS–2474–NC]

Medicaid and CHIP Programs; Initial Core Set of Children's Healthcare Quality Measures for Voluntary Use by Medicaid and CHIP Programs

AGENCY: Office of the Secretary, HHS.

ACTION: Notice with comment period.

SUMMARY: This notice identifies and solicits public comments on the initial, recommended core set of children's health care quality measures for voluntary use by State programs administered under titles XIX and XXI of the Social Security Act, health insurance issuers and managed care entities that enter into contracts with Medicaid and Children's Health Insurance Programs, and providers of items and services under these programs, in accordance with the Children's Health Insurance Program Reauthorization Act of 2009 (Pub. L. 111–3). This notice also discusses steps already underway to facilitate the programs' voluntary use of the children's health care quality measures. In addition, this notice solicits comments on how the steps might be enhanced, and recommendations for additional steps to facilitate use of the measures.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 1, 2010.

ADDRESSES: Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of two ways (please choose only one of the ways listed):

1. *Electronic Mail. CHIPRAquality measures@ahrq.hhs.gov*.

2. *Regular Mail.* Agency for Healthcare Research and Quality, Attention: Office of Extramural Research, Education, and Priority Populations—Public Comment, CHIPRA Core Measures, 540 Gaither Rd., Rockville, MD 20850.

Please note that all submissions may be posted without change to *http://www.AHRQ.gov*, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: *CHIPRAqualitymeasures@AHRQ.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On February 4, 2009, the Congress enacted the Children's Health Insurance Program Reauthorization Act (CHIPRA) of 2009 (Pub. L. 111–3). Section 401(a) of the legislation amended the Social Security Act (the Act), to establish section 1139A (42 U.S.C. 1320b-9a). This section requires the Secretary to identify and publish for general comment an initial, recommended core set of child health quality measures for use by State programs administered under titles XIX and XXI of the Act, health insurance issuers and managed care entities that enter into contracts with such programs, and providers of items and services under such programs. The statute requires that the

Secretary identify and publish these measures by January 1, 2010. The Secretary delegated this task to the Centers for Medicare & Medicaid Services (CMS). A ''Memorandum of Understanding'' was signed with the Agency for Healthcare Research and Quality (AHRQ), by which CMS and AHRQ would collaborate to make recommendations for the initial core set of children's health care quality measures to be posted for public comment. The initial core set is intended to be used voluntarily by Medicaid and the Children's Health Insurance Program (CHIP).

The initial core set of children's health care quality measures for voluntary use by Medicaid and CHIP programs was developed in consultation with organizations representing the stakeholder categories set out at section 1139A(b)(3) of the Act (including States; health care providers specializing in pediatric health and dentistry; health care providers that furnish primary health care to children and families who live in urban and rural medically underserved communities or who are members of distinct population subgroups at heightened risk for poor health outcomes; national organizations representing children and families; individuals and organizations with health care quality measurement expertise; and other organizations involved in the advancement of evidence-based measures of health care).

Measures for consideration for the initial core set were compiled from ''existing quality of care measures for children that are in use under public and privately sponsored health care coverage arrangements, or that are part of reporting systems that measure both the presence and duration of health insurance coverage over time'' as required by section 1139A(a)(2) of the Act.

The statute requires that the initial core set of child health quality measures include the following:

1. The duration of children's health insurance coverage over a 12-month time period.

2. The availability and effectiveness of a full range of preventive services, treatments, and services for acute conditions, including services to promote healthy birth, prevent and treat premature birth, and detect the presence or risk of physical or mental conditions that could adversely affect growth and development; and treatments to correct or ameliorate the effects of physical and mental conditions, including chronic conditions in infants, young children, school-age children, and adolescents.

3. The availability of care in a range of ambulatory and inpatient health care settings in which such care is furnished.

4. The types of measures that, taken together, can be used to estimate the overall national quality of health care for children, including children with special needs, and to perform comparative analyses of pediatric health care quality and racial, ethnic, and socioeconomic disparities in child health and health care for children.

To help facilitate an evidence-informed and transparent process for making recommendations, AHRQ's National Advisory Council on Healthcare Research and Quality created a Subcommittee on Children's Healthcare Quality Measures for Medicaid and CHIP programs (the ''Subcommittee''). The Subcommittee held public meetings, and considered public comments and measure nominations throughout their deliberations. Subcommittee members were provided with standard definitions, criteria, and objective information to facilitate scoring of measures for validity, feasibility, and importance over several iterations of measure consideration. The Subcommittee's recommendations were reported to the Chair of AHRQ's National Advisory Council on Healthcare Research and Quality and subsequently considered further by Medicaid and CHIP officials, as well as staff in the Office of the Secretary of the Department of Health and Human Services (HHS) prior to this public posting. Extensive details regarding the process, the measures recommended, and other considerations regarding the initial core set can be found at *http://www.ahrq.gov/chip/corebackgrnd.htm*. We are now soliciting additional comments from the public to help determine which measures should remain in the core set, which measures may need further development to enhance their validity and feasibility, and the nature of technical assistance and other resources required before State Medicaid and CHIP programs and health care providers can be expected to implement and report on these measures. In submitting comments, it is important to consider the kinds of activities already under way at HHS to facilitate making the measures more feasible and valid for use by the States for reporting across all Medicaid and CHIP programs (for example, managed care, fee-for-service and enrollees).

HHS will be making improvements and enhancements to the core set of measures as a result of the following:

- Public comment on the initial, recommended core measure set.
- Products developed by a pediatric quality measures program of grants and contracts to begin in 2010 (section 1139A(b) of the Act).
- Products stimulated by CMS's CHIPRA Quality Demonstration Grants, including evaluation and experimentation with the measures and development of an electronic health record format for children's health care (section 1139A(d) of the Act).
- Other advancements and improvements to children's health care quality measures (such as annual quality reporting as required under section 1139A(a)(4) of the Act).

Section 1139A(b)(5) of the Act directs that an improved, evidence-based core measure set is to be available by January 1, 2013, to be feasible for use by a broad range of providers, payers, and programs, both public and private (42 U.S.C. 1320b-9a).

To further these efforts, AHRQ and CMS are currently working to continue or implement the following initiatives:

1. Establishing methodologies to create measure specifications that are applicable to all Medicaid and CHIP enrollees, and suitable for identifying disparities in quality by race, ethnicity, socioeconomic status, and special health care needs status, as required by CHIPRA.

2. Providing technical assistance to States to facilitate implementation of the initial, recommended core measure set.

3. Using a public process for the pediatric quality measures grants and contracts program to build on priorities identified during the 2009 identification of the initial, recommended core set. Priority topics already identified include quality measures for: mental health and substance abuse services for children, other specialty services, inpatient care, duration of enrollment and coverage, medical home and other integrated health care delivery mechanisms, and availability of services.

4. Considering ways to align State reporting requirements across CHIPRA provisions, with Early and Periodic Screening, Diagnostic and Treatment Services (EPSDT) via CMS 416 reporting, and with annual reporting requirements for CHIP.

5. Coordinating quality measurement efforts with payment reform strategies, health information technology and electronic health record initiatives, and

6. Working with States to identify the best formats for sharing Medicaid and CHIP quality measurement data, including when and how state reports should be made publicly available.

7. Continuing to work with States and national stakeholders to develop

national intervention strategies for improving health care quality and outcomes for children (for example, Medicaid Transformation Grants and the CHIPRA Quality Demonstration Grants).

8. Continuing development and implementation of the Federal-State National Quality Framework in alignment with CHIPRA initiatives for improving the quality of care for children.

9. Due to the concurrent CHIPRA and American Recovery and Reinvestment Act (ARRA) HIT implementation activities, CMS will align the two programs and strive to create efficiencies for States and pediatric providers, where applicable, by prioritizing consistency in measure selection for pediatric providers.

II. Categories of the Initial, Recommended Core Set of Children's Healthcare Quality Measures

The basic categories of the initial, recommended core set of children's health care quality measures are set forth below. For full specifications of each measure and summaries of the rationales behind each recommended measure, see the background paper for this **Federal Register** notice at *http://www.ahrq.gov/chip/corebackgrnd.htm*. Measures that have received National Quality Forum (NQF) endorsement are indicated with the relevant number.

MEASURES RECOMMENDED FOR INITIAL CORE SET OF CHILDREN'S HEALTHCARE QUALITY FOR VOLUNTARY REPORTING BY MEDICAID AND CHIP PROGRAMS, MEASURE LABELS BY LEGISLATIVE CATEGORY

Measure number	Legislative measure topic/Subtopic/Current measure label
	PREVENTION AND HEALTH PROMOTION
	Prenatal/Perinatal
1	Frequency of ongoing prenatal care.
2	Timeliness of prenatal care—the percentage of deliveries that received a prenatal care visit as a member of the organization in the first trimester or within 42 days of enrollment in the organization.
3	Percent of live births weighing less than 2,500 grams.
4	Cesarean Rate for low-risk first birth women [NQF #0471].
	Immunizations
5	Childhood immunization status [NQF #0038].
6	Immunizations for adolescents.
	Screening
7	BMI documentation 2–18 year olds [NQF #0024].
8	Screening using standardized screening tools for potential delays in social and emotional development—Assuring Better Child Health and Development (ABCD) initiative measures.
9	Chlamydia screening for women [NQF #0033].
	Well-child Care Visits (WCV)
10	WCVs in the first 15 months of life.
11	WCVs in the third, fourth, fifth and sixth years of life.
12	WCV for 12–21 yrs of age—with PCP or OB–GYN.
	Dental
13	Total eligibles receiving preventive dental services (EPSDT measure Line 12B).
	MANAGEMENT OF ACUTE CONDITIONS
	Upper Respiratory—Appropriate Use of Antibiotics
14	Appropriate testing for children with pharyngitis [NQF #0002].
15	Otitis Media with Effusion—avoidance of inappropriate use of systemic antimicrobials—ages 2–12.
	Dental
16	Total EPSDT eligibles who received dental treatment services (EPSDT CMS Form 416, Line 12C).
	Emergency Department
17	Emergency Department (ED) Utilization—Average number of ED visits per member per reporting period.
	Inpatient Safety
18	Pediatric catheter-associated blood stream infection rates (PICU and NICU) [NQF #0139].
	MANAGEMENT OF CHRONIC CONDITIONS
	Asthma
19	Annual number of asthma patients (≥ 1 year old) with ≥ 1 asthma related ER visit (S/AL Medicaid Program).

MEASURES RECOMMENDED FOR INITIAL CORE SET OF CHILDREN'S HEALTHCARE QUALITY FOR VOLUNTARY REPORTING BY MEDICAID AND CHIP PROGRAMS, MEASURE LABELS BY LEGISLATIVE CATEGORY—Continued

Measure number	Legislative measure topic/Subtopic/Current measure label
	ADHD
20	Follow-up care for children prescribed attention-deficit/hyperactivity disorder (ADHD) medication (Continuation and Maintenance Phase) [NQF #108].
	Mental Health
21	Follow up after hospitalization for mental illness.
	Diabetes
22	Annual hemoglobin A1C testing (all children and adolescents diagnosed with diabetes).
	FAMILY EXPERIENCES OF CARE
23	CAHPS® Health Plan Survey 4.0, Child Version including Medicaid and Children with Chronic Conditions supplemental items.
	AVAILABILITY
24	Children and adolescents' access to primary care practitioners (PCP), by age and total.

Comments on the measures themselves are encouraged to:

- Specify which of the measures are being addressed with each comment.
- Explain views and reasoning clearly.

In addition, comments are invited on the AHRQ and CMS plans to enhance the initial, recommended core measure set so that they can be collected most efficiently and accurately across all Medicaid and CHIP programs, providers, and enrollees.

We strongly encourage comments to be as succinct as possible (250 words or less recommended, with additional supporting data allowed).

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

IV. Regulatory Impact Analysis

As this notice does not meet the significance criteria of Executive Order 12866, it was not reviewed by the Office of Management and Budget.

Authority: Section XIX and XXI of the Social Security Act (42 U.S.C. 13206 through 9a)

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: December 22, 2009.

Kathleen Sebelius,

Secretary.

[FR Doc. E9–30802 Filed 12–28–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Novel Technologies in Newborn Screening.

Date: January 14, 2010.

Time: 2 a.m. to 3:30 p.m.

Agenda: To review and evaluate concept review.

Place: National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Rockville, MD 20852. (Telephone Conference Call)

Contact Person: Sathasiva B. Kandasamy, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892–9304, (301) 435–6680, *skandasa@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: December 18, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–30680 Filed 12–28–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Adoption of ANA Program Policies and Procedures

AGENCY: Administration for Native Americans (ANA), HHS.

ACTION: Notice of Public Comment on the Proposed Adoption of ANA Program Policies and Procedures.

SUMMARY: Pursuant to Section 814 of the Native American Programs Act of 1974 (NAPA), as amended, the Administration for Native Americans is