normal metabolizer) could be given for those patients.

Based on prescription dispensing data obtained from a proprietary drug utilization database available to FDA, the Agency understands that the number of patients ages 0 to 11 who were dispensed codeine-containing analgesic products decreased from an estimated 735,000 patients in 2013 to 230,000 patients in 2017. Following the addition of the contraindication of codeine-containing drug products in children under 12 years of age to the codeine product labeling in August 2017, FDA has seen the prescription use of codeine decline further to 84,000 patients ages 0 to less than 12 years of age in 2018.[4]

II. Additional Issues for Consideration and Request for Information

FDA is soliciting information and comment from stakeholders regarding the issues described in this document. In addition to any other aspects of these issues that stakeholders may care to comment upon, FDA is interested in answers to the following questions in particular:

Topic 1: Pain Management in Children Under 12 Years of Age (for Prescribers and Other Stakeholders, as Appropriate)

1. What factors do you consider in choosing to prescribe an opioid analgesic for children under 12 years of age who require treatment for recurrent episodes of acute pain (*e.g.,* severity of pain, lack of response to other analgesics, or the specific disease, such as children with sickle cell disease-related pain crises)?

2. Which pediatric populations, other than children with sickle cell disease, typically use an opioid analgesic for recurrent episodes of acute pain?

3. What role, if any, do you see for codeine/acetaminophen combination drug products in the treatment of children under 12 years of age with recurrent episodes of acute pain?

4. What is your institution/department/clinical practice's recommended approach (or specific formulary options) for selecting an opioid analgesic for a child under 12 years of age? Was your institution/department/clinical practice's current approach modified following FDA's August 2017 codeine labeling revision that contraindicated codeine-containing drug products in children under 12 years of age? If there is not a recommended approach, what opioid analgesics are typically prescribed in your practice to patients under 12 years of age?

5. In your view/experience, is the contraindication for use of codeine/acetaminophen combination drug products in children under 12 years of age hampering optimal patient care?

6. What are the issues you have faced regarding urgent access to opioid analgesics (*e.g.,* after hours, on weekends, and holidays) for a child under 12 years of age with recurrent episodes of acute pain requiring an opioid analgesic?

a. For clinicians: If you have had to face these issues, how do they impact prescribing decisions? For example, would you consider giving a hard copy prescription for a small amount of opioid analgesic to be used in urgent or after-hours situations so the patient can avoid making a visit for urgent/emergency care?

b. For caregivers/patient advocates: How have you handled these issues?

Topic 2: CYP2D6 Genotyping Tests (for Prescribers and Technical Experts)

1. Would amending the contraindication to provide for CYP2D6 genotyping for children under 12 years of age prior to prescription of codeine-containing drug products change your clinical practice?

2. Have you utilized a CYP2D6 genotyping test when determining which opioid analgesic to select for a child under 12 years of age who has recurrent acute pain severe enough to warrant treatment with an opioid analgesic? Describe why or why not.

3. Describe your experience with interpreting CYP2D6 genotyping test results and using those results to make drug prescribing decisions.

4. For a CYP2D6 genotyping test to appropriately identify patients who can safely receive a codeine-containing drug product, what is the minimum genotyping accuracy and minimum acceptable coverage of the currently known genotypes that typically result in a poor metabolizer or ultra-rapid metabolizer phenotype?

5. Regarding detection of ultra-rapid metabolizers, what is the type of test output that would be needed for copy number? Is a result of ''duplication present'' (*i.e.,* more than one copy) sufficient, or is specific quantitation of the number of copies needed?

Topic 3: E-Prescribing Availability (for Prescribers)

1. Is e-prescribing available in your institution/department/clinical practice?

2. What is your practice regarding e-prescribing of Schedule II opioids? Are there any limitations in your institution/department/clinical practice for e-prescribing of Schedule II opioids?

3. Would you e-prescribe a Schedule II opioid based on a telephone discussion with a child's caregiver? Would you e-prescribe any opioid (including those in Schedule III and Schedule IV) based on a telephone discussion with a child's caregiver? Describe why or why not.

4. If you do not have e-prescribing available, how does that impact your ability to prescribe Schedule II opioids for children under 12 years of age, particularly with recurrent acute pain episodes?

Dated: June 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–13974 Filed 6–26–20; 8:45 am]

BILLING CODE 4164–01–P

[4] Source: IQVIA Total Patient Tracker™, 2013–2018. Data extracted May 2018 and June 2019.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Information Technology Advisory Committee 2020 Schedule—Revised; Meeting

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), HHS.

ACTION: Notice of meeting.

SUMMARY: The Health Information Technology Advisory Committee (HITAC) was established in accordance with section 4003(e) of the 21st Century Cures Act and the Federal Advisory Committee Act. The HITAC, among other things, identifies priorities for standards adoption and makes recommendations to the National Coordinator for Health Information Technology (National Coordinator). The HITAC will hold public meetings throughout 2020. See list of public meetings below.

FOR FURTHER INFORMATION CONTACT: Lauren Richie, Designated Federal Officer, at *Lauren.Richie@hhs.gov,* (202) 205–7674.

SUPPLEMENTARY INFORMATION: Section 4003(e) of the 21st Century Cures Act (Pub. L. 114–255) establishes the Health Information Technology Advisory Committee (referred to as the ''HITAC''). The HITAC will be governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92–463), as amended, (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

Composition

The HITAC is comprised of at least 25 members, of which:

- No fewer than 2 members are advocates for patients or consumers of health information technology;
- 3 members are appointed by the HHS Secretary
  - 1 of whom shall be appointed to represent the Department of Health and Human Services and
  - 1 of whom shall be a public health official;
- 2 members are appointed by the majority leader of the Senate;
- 2 members are appointed by the minority leader of the Senate;
- 2 members are appointed by the Speaker of the House of Representatives;
- 2 members are appointed by the minority leader of the House of Representatives; and
- Other members are appointed by the Comptroller General of the United States.

Members will serve for one-, two-, or three-year terms. All members may be reappointed for a subsequent three-year term. Each member is limited to two three-year terms, not to exceed six years of service. After establishment, members shall be appointed for a three-year term. Members serve without pay, but will be provided per-diem and travel costs for committee services.

Recommendations

The HITAC recommendations to the National Coordinator are publicly available at *https://www.healthit.gov/topic/federal-advisory-committees/recommendations-national-coordinator-health-it.*

Public Meetings

The revised schedule of meetings to be held in 2020 is as follows:

- January 15, 2020 from approximately 9:30 a.m. to 2:30 p.m./ Eastern Time at the Washington Plaza Hotel, 10 Thomas Circle NW, Washington, DC 20005
- February 19, 2020 from approximately 9:30 a.m. to 2:30 p.m./ Eastern Time (virtual meeting)
- March 18, 2020 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)
- March 26, 2020 from approximately 10:30 a.m. to 1:30 p.m./Eastern Time (virtual meeting)
- April 15, 2020 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)
- May 20, 2020 from approximately 9:30 a .m. to 2:30 p.m./Eastern Time (virtual meeting)
- (June 17, 2020 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)
- September 9, 2020 from approximately 9:30 a.m. to 2:30 p.m./ Eastern Time (virtual meeting)
- October 21, 2020 from approximately 9:30 a.m. to 2:30 p.m./ Eastern Time (virtual meeting)
- November 10, 2020 from approximately 9:30 a.m. to 2:30 p.m./ Eastern Time (virtual meeting)

All meetings are open to the public. Additional meetings may be scheduled as needed. For web conference instructions and the most up-to-date information, please visit the HITAC calendar on the ONC website,*https://www.healthit.gov/topic/federal-advisory-committees/hitac-calendar.*

Contact Person for Meetings: Lauren Richie, *lauren.richie@hhs.gov* . A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Please email Lauren Richie for the most current information about meetings.

Agenda: As outlined in the 21st Century Cures Act, the HITAC will develop and submit recommendations to the National Coordinator on the topics of interoperability, privacy and security, and patient access. In addition, the committee will also address any administrative matters and hear periodic reports from ONC. ONC intends to make background material available to the public no later than 24 hours prior to the meeting start time. If ONC is unable to post the background material on its website prior to the meeting, the material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on ONC's website after the meeting, at *http://www.healthit.gov/hitac.*

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person prior to the meeting date. An oral public comment period will be scheduled at each meeting. Time allotted for each presentation will be limited to three minutes. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled public comment period, ONC will take written comments after the meeting.

Persons attending ONC's HITAC meetings are advised that the agency is not responsible for providing wireless access or access to electrical outlets.

ONC welcomes the attendance of the public at its HITAC meetings. Seating is limited at the location, and ONC will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Lauren Richie at least seven (7) days in advance of the meeting.

Notice of these meetings are given under the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App. 2).

Dated: June 23, 2020.

Cassandra Hadley,

Office of Policy, Office of the National Coordinator for Health Information Technology.

[FR Doc. 2020–13978 Filed 6–26–20; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 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 contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NHP MHC and KIR Allele Discovery and Typing Technology Development.

Date: July 21, 2020.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41 Rockville, MD 20892 (Virtual Meeting).

Contact Person: Tara Capece, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41 Rockville, MD 20852 301–761–7854 *capecet2@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology,