treated, may lead to significant morbidity and mortality. When administered quickly after an opioid overdose, naloxone, an opioid antagonist, can save lives. Naloxone is currently approved as a prescription drug, but it is not approved for nonprescription use. As part of a wide governmental effort to address the national crisis of opioid overdose deaths, the Agency has identified broader availability of naloxone, including potential nonprescription availability, as one means to help reduce overdose deaths.

To support approval of a drug for nonprescription use, the sponsor of the drug product typically (among other things) conducts one or more consumer behavior studies to demonstrate that consumers would be able to use the drug product safely and effectively in the nonprescription setting without the supervision of a healthcare professional. Some stakeholders have identified the need to perform these studies as a barrier to development of a nonprescription naloxone drug product. To help address this concern, FDA developed a model DFL for a potential nonprescription naloxone drug product. The model DFL is intended to contain adequate information (except for individual device-specific information, such as how to use a particular injector or spray device, which would be added by the product sponsor) that a consumer would need to administer naloxone safely and effectively for its intended use in the nonprescription setting. Consumer comprehension of the model DFL has been iteratively tested by an independent research contractor in a prespecified research design involving over 700 participants across a wide range of potential nonprescription naloxone users. These participants included people who use heroin, people who use prescription opioids, family and friends of people who use opioids, adolescents, and members of the general public.

After completion of the label comprehension study, an FDA review team that was not involved in the design or conduct of the study reviewed the study report and determined that the comprehension results are adequate. FDA has determined that the model DFL can be made publicly available so that sponsors who wish to pursue development of a nonprescription naloxone product can use the model DFL in their development program. A sponsor would need to add its device-specific information to the model DFL and retest that information to demonstrate that consumers understand the information within the context of the overall DFL. The model DFL comes in two versions (one for use with a nasal spray and one for use with an injector), but the device-specific instructions in each version are placeholders that have not been tested for comprehension or human factors performance, and sponsors will need to replace these placeholders with their own device-specific information and retest it appropriately.

FDA strongly encourages sponsors of potential nonprescription naloxone drug products to request a meeting to discuss their development program with the Division of Nonprescription Drug Products. For information on sponsor meetings with FDA, sponsors can refer to the draft guidance for industry ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm590547.pdf.*

II. Electronic Access

Persons with access to the internet may obtain the model DFLs at *https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM629320.pdf* and *https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM629321.pdf.*

Dated: March 6, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–04357 Filed 3–8–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

''Low-Income Levels'' Used for Various Health Professions and Nursing Programs Authorized in the Public Health Service Act

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is updating income levels used to identify a ''low-income family'' for the purpose of determining eligibility for programs that provide health professions and nursing training to individuals from disadvantaged backgrounds. These various programs are authorized in Titles III, VII, and VIII of the Public Health Service Act.

SUPPLEMENTARY INFORMATION: HHS periodically publishes in the **Federal Register** low-income levels to be used by institutions receiving grants and cooperative agreements to determine eligibility for programs providing training for (1) disadvantaged individuals, (2) individuals from disadvantaged backgrounds, or (3) individuals from low-income families.

Many health professions and nursing grant and cooperative agreement awardees use the low-income levels to determine whether potential program participants are from an economically disadvantaged background and would be eligible to participate in the program, as well as to determine the amount of funding the individual receives. Awards are generally made to accredited schools of allopathic medicine, osteopathic medicine, public health, dentistry, veterinary medicine, optometry, pharmacy, allied health, podiatric medicine, nursing, and chiropractic; public or private nonprofit schools, which offer graduate programs in behavioral health and mental health practice; and other public or private nonprofit health or education entities to assist the disadvantaged to enter and graduate from health professions and nursing schools. Some programs provide for the repayment of health professions or nursing education loans for disadvantaged students.

A ''low-income family/household'' for programs included in Titles III, VII, and VIII of the Public Health Service Act is defined as having an annual income that does not exceed 200 percent of the Department's poverty guidelines. A family is a group of two or more individuals related by birth, marriage, or adoption who live together.

Most HRSA programs use the income of a student's parents to compute low-income status. However, a ''household'' may potentially be only one person. Other HRSA programs, depending upon the legislative intent of the program, the programmatic purpose related to income level, as well as the age and circumstances of the participant, will apply these low-income standards to the individual student to determine eligibility, as long as he or she is not listed as a dependent on the tax form of his or her parent(s). Each program announces the rationale and choice of methodology for determining low-income levels in program guidance.

Low-income levels are adjusted annually based on HHS' poverty guidelines. HHS' poverty guidelines are based on poverty thresholds published by the U.S. Census Bureau, adjusted annually for changes in the Consumer Price Index. The income figures below

have been updated to reflect the Department's 2019 poverty guidelines as published in 84 FR 1167 (February 1, 2019).

LOW-INCOME LEVELS BASED ON THE 2019 POVERTY GUIDELINES FOR THE 48 CONTIGUOUS STATES AND THE DISTRICT OF COLUMBIA

Persons in family/household *	Income Level **
1	$24,980
2	33,820
3	42,660
4	51,500
5	60,340
6	69,180
7	78,020
8	86,860

For families with more than 8 persons, add $8,840 for each additional person.

LOW-INCOME LEVELS BASED ON THE 2019 POVERTY GUIDELINES FOR ALASKA

Persons in family/household *	Income Level **
1	$31,200
2	42,260
3	53,320
4	64,380
5	75,440
6	86,500
7	97,560
8	108,620

For families with more than 8 persons, add $11,060 for each additional person.

LOW-INCOME LEVELS BASED ON THE 2019 POVERTY GUIDELINES FOR HAWAII

Persons in family/household *	Income Level **
1	$28,760
2	38,920
3	49,080
4	59,240
5	69,400
6	79,560
7	89,720
8	99,880

For families with more than 8 persons, add $10,160 for each additional person.

* Includes only dependents listed on federal income tax forms.

** Adjusted gross income for calendar year 2018.

Separate poverty guidelines figures for Alaska and Hawaii reflect Office of Economic Opportunity administrative practice beginning in the 1966–1970 period since the U.S. Census Bureau poverty thresholds do not have separate figures for Alaska and Hawaii. The poverty guidelines are not defined for Puerto Rico or other outlying jurisdictions. Puerto Rico and other outlying jurisdictions shall use income guidelines for the 48 Contiguous States and the District of Columbia.

Dated: March 4, 2019.

George Sigounas,

Administrator.

[FR Doc. 2019–04407 Filed 3–8–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held on April 8, 2019, for the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council). The meeting will be open to the public via teleconference. Pre-registration is required for members of the public who wish to attend the meeting via teleconference. Individuals who wish to send in their public comments should send an email to *CARB@hhs.gov.* Registration information is available on the website *http://www.hhs.gov/ash/carb/* and must be completed by April 2, 2019. Additional information about registering for the meeting and providing public comments can be obtained at *http://www.hhs.gov/ash/carb/* on the Meetings page.

DATES: The meeting is scheduled to be held on April 8, 2019, from 12:00 p.m. to 2:00 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the website for the Advisory Council at *http://www.hhs.gov/ash/carb/* when this information becomes available. Pre-registration for attending the meeting is required to be completed no later than April 2, 2019.

ADDRESSES: Instructions regarding attending this meeting virtually will be posted one week prior to the meeting at: *http://www.hhs.gov/ash/carb/.*

FOR FURTHER INFORMATION CONTACT: Jomana Musmar, Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, Room L133, Switzer Building, 330 C. St. SW, Washington, DC 20201. Phone: (202) 690–5566; email: *CARB@hhs.gov.*

SUPPLEMENTARY INFORMATION: Under Executive Order 13676, dated September 18, 2014, authority was given to the Secretary of HHS to establish the Advisory Council, in consultation with the Secretaries of Defense and Agriculture. Activities of the Advisory Council are governed by the provisions of Public Law 92–463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

The Advisory Council will provide advice, information, and recommendations to the Secretary of HHS regarding programs and policies intended to support and evaluate the implementation of Executive Order 13676, including the National Strategy for Combating Antibiotic-Resistant Bacteria and the National Action Plan for Combating Antibiotic-Resistant Bacteria. The Advisory Council shall function solely for advisory purposes.

In carrying out its mission, the Advisory Council will provide advice, information, and recommendations to the Secretary regarding programs and policies intended to preserve the effectiveness of antibiotics by optimizing their use; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial infections; prevent the transmission of antibiotic-resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research on new treatments for bacterial infections; develop alternatives to antibiotics for agricultural purposes; maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and improve international coordination of efforts to combat antibiotic resistance.

The public meeting will be dedicated to deliberation and vote of the report with recommendation from the Immediate Action Subcommittee of the Advisory Council. The meeting agenda will be posted on the Advisory Council website at *http://www.hhs.gov/ash/carb/* when it has been finalized. All agenda items are tentative and subject to change.

Instructions regarding attending this meeting virtually will be posted one