

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

NASONEX (mometasone furoate) nasal spray, 0.05 mg/spray 50 (mcg), is the subject of NDA 020762, held by Organon LLC, and initially approved on October 1, 1997. NASONEX (mometasone furoate) nasal spray, 0.05 mg/spray 50 (mcg) is a corticosteroid indicated for:

- Treatment of nasal symptoms of allergic rhinitis in patients 2 years of age and older;
- treatment of nasal congestion associated with seasonal allergic rhinitis in patients 2 years of age or older;
- prophylaxis of seasonal allergic rhinitis in patients 12 years of age or older; and
- treatment of nasal polyps in patients 18 years of age or older.

In a letter dated December 4, 2020, Merck Sharp and Dohme Corp., a subsidiary of Merck and Co., Inc., notified FDA that NASONEX (mometasone furoate) nasal spray, 0.05 mg/spray 50 (mcg) was being discontinued, and FDA moved the drug product to the “Discontinued Drug Product List” section of the Orange Book.

Aurobindo Pharma Ltd. submitted a citizen petition dated January 14, 2022 (Docket No. FDA-2022-P-0077), under 21 CFR 10.30, requesting that the Agency determine whether NASONEX (mometasone furoate) nasal spray, 0.05 mg/spray 50 (mcg), was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under

§ 314.161 that NASONEX (mometasone furoate) nasal spray, 0.05 mg/spray 50 (mcg) was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that NASONEX (mometasone furoate) nasal spray, 0.05 mg/spray 50 (mcg) was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of NASONEX (mometasone furoate) nasal spray, 0.05 mg/spray 50 (mcg) from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list NASONEX (mometasone furoate) nasal spray, 0.05 mg/spray 50 (mcg), in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: April 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-07563 Filed 4-7-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information (RFI): 2022 HHS Environmental Justice Strategy and Implementation Plan Draft Outline

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

ACTION: Notice of request for information.

SUMMARY: The Department of Health and Human Services (HHS) is issuing this Request for Information (RFI) to receive input from the public on HHS’ draft outline to further the development of the 2022 Environmental Justice Strategy

and Implementation Plan. Consistent with the policy of this administration directing HHS to make achieving environmental justice part of its mission, HHS would like to identify priority actions and strategies to best address environmental injustices and health inequities for people of color, disadvantaged, vulnerable, low-income, marginalized, and indigenous populations. With the engagement of and input from the public, the 2022 Environmental Justice Strategy and Implementation Plan will serve as a guide to confront environmental and health disparities and implement a multifaceted approach that will serve vulnerable populations and communities disproportionately impacted by environmental burdens.

DATES: To be assured consideration, comments must be received at the email address provided below, no later than midnight Eastern Time (ET) on May 19, 2022. HHS will not reply individually to responders but will consider all comments submitted by the deadline. Do not provide confidential information as comments may be published or otherwise used for agency purposes.

ADDRESSES: Please submit all responses via email to OASHcomments@hhs.gov as a Word document or in the body of an email.

FOR FURTHER INFORMATION CONTACT: Dr. LaToria Whitehead, Senior Public Health Analyst, email: ceq6@cdc.gov, phone: (770) 488-3633.

SUPPLEMENTARY INFORMATION: The mission of the U.S. Department of Health and Human Services is to enhance the health and well-being of Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services. For years studies have demonstrated that people of color and disadvantaged, vulnerable, low-income, marginalized, and indigenous populations are disproportionately burdened by environmental hazards.¹ These populations are often exposed to unhealthy land uses, poor air and water quality, dilapidated housing, lead exposure, and other environmental threats that drive health disparities. Many of these communities are underserved and surrounded by social inequities such as job insecurity, underemployment, linguistic isolation, underperforming schools, noise, crowded homes, lack of access to

¹ Toxic Wastes and Race at Twenty 1987–2007. A Report Prepared for the United Church of Christ Justice & Witness Ministries. Principal Authors: Bullard R, Mohai P, Saha R, Wright B. 2007.

healthy foods and transportation, and limitations on access to and participation in the decision-making processes.^{2,3} The combination of environmental risks and social inequities creates a cumulative, disproportionate impact that hinders optimal health and environmental justice for these populations.⁴ The Environmental Protection Agency defines Environmental Justice (EJ) as “the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies”.⁵

On January 27, 2021, President Biden directed the Department of Health and Human Services to make achieving environmental justice part of its mission by developing programs, policies, and activities to address the disproportionately high and adverse human health, environmental and climate-related and other cumulative impacts on disadvantaged communities.⁶ In 1994, President Clinton signed Executive Order 12898, *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*, also directing federal agencies to “make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations.” Executive Order 12898 required each agency to develop an agency-wide environmental justice strategy specific to that agency’s mission. In response, HHS issued its first Environmental Justice Strategy in 1995. Federal environmental justice

efforts were reinvigorated in 2010 and in 2012, and again, HHS responded with release of an updated Environmental Justice Strategy and Implementation Plan.⁷ Currently, to support the executive order initiatives, and to pursue the Administration’s policy priorities for environmental justice, a revised strategy focused on short-term concrete actions, alongside thoughtful long-term planning, is required. OASH has convened and tasked the HHS Environmental Justice Working Group to develop the 2022 HHS Environmental Justice Strategy and Implementation Plan.

The purpose of this Request for Information (RFI) is to seek public comment on the 2022 HHS Environmental Justice Strategy and Implementation Plan *Draft Outline*. The goal of the HHS Environmental Justice Strategy and Implementation Plan is to provide direction for HHS efforts, pursue the Administration’s policy priorities and identify priority actions for environmental justice. The draft outline provides a general overview and a platform of how the plan will be structured. Within the outline, each strategic element is aligned to priority actions that HHS will carry out. Please see the *Draft Strategy Outline* below, followed by a request for information in the form of questions to the public.

U.S. Department of Health and Human Services 2022 Environmental Justice Strategy and Implementation Plan Draft Outline

The 2022 HHS Environmental Justice Strategy and Implementation Plan will likely include six interrelated strategic elements that mirror the 2012 HHS Environmental Justice Strategy. The elements include two new strategic elements: (1) Partnerships and Community Engagement and (2) Performance Measures. The additional elements align to Executive Order 12898 to engage and partner with disadvantaged populations in building sustainable and healthy communities and creating performance measures to evaluate the process and the outcomes of activities that address adverse environmental conditions. The six proposed strategic elements are:

- (1) *Services*
- (2) *Partnerships and Community Engagement*
- (3) *Policy Development and Dissemination*

- (4) *Research and Data Collection, Analysis, and Utilization*
- (5) *Education and Training*
- (6) *Performance Measures*

For each strategic element, the 2022 HHS EJ Strategy will include priority actions to be undertaken by designated HHS Operating Divisions and Staff Divisions.

I. Services

- Priority Action(s)
 - Increase linguistic and culturally appropriate outreach to racial and ethnic minority, low-income, and Indigenous populations, and Native American persons with disproportionately high and adverse environmental exposures to raise their awareness of the availability of technical assistance for applying for HHS funding.
 - Expand funding opportunities to disadvantaged communities for economic development and social services.

II. Partnerships and Community Engagement (Public Engagement)

- Priority Action(s)
 - Establish partnerships with disadvantaged communities to assess and address disproportionate environmental exposures and health risks.
 - Partner with offices and departments with Title VI enforcement and compliance responsibilities to address environmental injustices and ensure that disadvantaged communities can effectively participate in and benefit from federally funded public health and social service programs and activities without discrimination.
 - Work with federal partners and various stakeholders to provide coordinated technical assistance and support to programs focused on disadvantaged communities.
 - Promote actions and seek resources to overcome participation barriers such as language and culture.

III. Policy Development and Implementation

- Priority Action(s)
 - Identify and provide technical assistance to HHS programs covered under the Justice40 Initiative to ensure 40 percent of the overall benefits the programs provide flow to disadvantaged communities.
 - Provide home cooling, weatherization, and/or low-cost home energy assistance to communities disproportionately affected by extreme weather events.

² Bullard RD, Johnson GS, Torres AO. *Environmental Health and Racial Equity in the United States. Building Environmentally Just, Sustainable, and Livable Communities*. Washington, DC: American Public Health Association Press. 2011.

³ Morello-Frosch R, Zuk M, Jerrett M, Shamasunder B. *Understanding the Cumulative Impacts of Inequalities in Environmental Health: Implications for Policy*. Health Affairs. 2011.

⁴ Cushing L, Morello-Frosch R, Wander M, Pastor M. *The Haves, the Have-Nots, and the Health of Everyone: The Relationship Between Social Inequality and Environmental Quality*. Annual Review of Public Health. 2015.

⁵ U.S. Environmental Protection Agency (EPA). *Environmental Justice*. Environmental Justice | US EPA.

⁶ Executive Order 14008. “*Tackling the Climate Crisis at Home and Abroad*.” 86 FR 7619 (January 27, 2021). See <https://www.federalregister.gov/documents/2021/02/01/2021-02177/tackling-the-climate-crisis-at-home-and-abroad>.

⁷ U.S. Department of Health and Human Services (HHS). 2012 Environmental Justice Strategy and Implementation Plan. See 2012 HHS ENVIRONMENTAL JUSTICE STRATEGY AND IMPLEMENTATION PLAN.

- Fund and implement training and workforce development programs that build skills and careers related to climate, natural disasters, environment, clean energy, clean transportation, housing, water and wastewater infrastructure, and legacy pollution reduction.

IV. Research and Data Collection, Analysis, Utilization

- Priority Action(s)
 - Support research that explores the multiple and complex factors contributing to minority health disparities, including but not limited to environmental factors acting independently or dependently across multiple social levels.
 - Support the spectrum of community engaged research including community-based participatory research and community led research. Additionally, strengthen authentic community engagement in planning, implementing, evaluating, and disseminating effective interventions for diseases disproportionately affecting disadvantaged communities and vulnerable populations.
 - Coordinate the design, dissemination, and utilization of an environmental justice and social vulnerability data dashboard and index, for identifying, tracking, and addressing environmental burden and health inequities in disadvantaged communities.
 - Report research data to communities using culturally appropriate and accessible methods.

V. Education and Training

- Priority Action(s)
 - Provide data, training, and technical assistance to disadvantaged communities and vulnerable populations at higher risk for exposure to harmful environmental and health hazards.
 - Deliver comprehensive training to increase opportunities for individuals from disadvantaged, overburdened, and underserved communities to obtain careers in environmental cleanup, construction, hazardous waste removal, and emergency response.
 - Develop guidance and templates to assist states and tribes in the communication of environmental and health risks to households and communities.
 - Develop environmental justice training programs for Federal staff, primary health care and public

health professionals, and policy and other decision-makers.

VI. Performance Measures (Evaluation)

- Priority Action(s)
 - Develop milestones and provide periodic progress to demonstrate accountability and progress.

HHS is requesting information from the public regarding the following questions:

Environmental Justice Core Principles

1. What *Environmental Justice Core Principles* should be included in the HHS EJ Strategy to advance environmental justice for disadvantaged communities?
2. How should HHS incorporate *Environmental Justice Core Principles* in the HHS EJ Strategy?

Strategic Elements

1. Do the *Strategic Elements* reflect relevant areas of environmental justice that address the needs of disadvantaged communities?
2. Are there additional *Strategic Elements* that should be included in the HHS EJ Strategy?

Priority Actions

1. Do the *Priority Actions* capture the urgent, environmental justice issues of today?
2. If not, what additional *Priority Actions* should be included within the HHS EJ Strategy?

Research and Data Tools

1. What research methods, research questions, and data tools should HHS use to address environmental justice and social determinants of health?

Additional Information

1. What other strategies can be included within the 2022 HHS Environmental Justice Strategy and Implementation Plan to address environmental justice and health equity issues for disadvantaged populations?

HHS encourages all potentially interested parties—individuals, associations, governmental, non-governmental organizations, academic institutions, and private sector entities—to respond. HHS is interested in the questions listed above, but respondents are welcome to address as many or as few as they choose and to address additional areas of interest not listed. To facilitate review of the

responses, please reference the question category and number in your response.

Arsenio Mataka,

Senior Advisor, Office of the Assistant Secretary for Health, Department of Health and Human Services.

[FR Doc. 2022–07514 Filed 4–7–22; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

RIN 0917–AA21

Reimbursement Rates for Calendar Year 2022

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: Notice is provided that the Acting Director of the Indian Health Service (IHS) has approved the rates for inpatient and outpatient medical care provided by the IHS facilities for Calendar Year 2022.

SUPPLEMENTARY INFORMATION: The Acting Director of the Indian Health Service (IHS), under the authority of sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248 and 249(b)), Public Law 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*), has approved the following rates for inpatient and outpatient medical care provided by IHS facilities for Calendar Year 2022 for Medicare and Medicaid beneficiaries, beneficiaries of other federal programs, and for recoveries under the Federal Medical Care Recovery Act (42 U.S.C. 2651–2653). The inpatient rates for Medicare Part A are excluded from the table below. That is because Medicare inpatient payments for IHS hospital facilities are made based on the prospective payment system, or (when IHS facilities are designated as Medicare Critical Access Hospitals) on a reasonable cost basis. Since the inpatient per diem rates set forth below do not include all physician services and practitioner services, additional payment shall be available to the extent that those services are provided.

Inpatient Hospital per Diem Rate
(Excludes Physician/Practitioner Services)

Calendar Year 2022

Lower 48 States: \$4,239

Alaska: \$3,583

Outpatient per Visit Rate (Excluding Medicare)

Calendar Year 2022

Lower 48 States: \$640