



**Physician (Ethicist)**  
**Department of Health and Human Services (DHHS)**  
**Food and Drug Administration (FDA)**  
**Office of the Commissioner (OC)**  
**Office of Clinical Policy and Programs (OCPP)**  
**Office of Pediatric Therapeutics (OPT)**

**Summary:**

The position is located in the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), Office of the Commissioner (OC), Office of Clinical Policy and Programs (OCPP), Office of Pediatric Therapeutics (OPT) and being filled under FDA's Title 21 hiring authority. This hiring authority was passed by Congress in December 2016, to improve FDA's ability to recruit and retain scientific, technical, and professional experts in certain occupational series that "support the development, review, and regulation of medical products." The FY23 Omnibus Appropriations Bill expanded the hiring authority to include cross-cutting positions and individuals that support the development, review, and regulation of food and cosmetics in addition to medical products. Both statutes amended the FD&C Act 21 USC. This hiring authority is a streamlined hiring authority, outlined in 21 USC 379d-3a, as amended by the 21st Century Cures Act of 2016, § 3072 and the Consolidated Appropriations Act of 2023, § 3624.

Learn More About This Agency:

***Become a part of the Department that touches the lives of every American.***

*At the [Department of Health and Human Services \(HHS\)](#) you can give back to your community, state, and country, by making a difference in the lives of Americans everywhere! HHS is the principal agency for protecting the health of citizens. Join HHS and help to make our world healthier, safer, and better for all Americans.*

The Food and Drug Administration is the regulatory, scientific, public health, and consumer protection agency responsible for ensuring that all human and animal drugs, and medical devices are safe and effective; that cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, and radiation emitting devices are safe; and that all such products marketed in the U.S. are adequately, truthfully and informatively labeled and safely and properly stored, transported, manufactured packaged and regulated.

Office of the Commissioner (OC) is responsible for the efficient and effective implementation of FDA's mission. To assist in those responsibilities, OC contains Super Offices that support specific organizational focus areas and administrative offices that manage operational staff needs. OC also oversees the newly established FDA Reimagined Human Foods Program.

The mission of the Office of Clinical Policy and Programs (OCP) is to advance the public health by developing, leading, and executing programs and cross-cutting initiatives that support FDA’s centers in making effective, safe, and innovative medical products available to the American people. OCP also coordinates and supports patient engagement activities across the medical product centers to foster awareness and collaboration with patients, caregivers, their advocates, and the FDA community.

The Office of Pediatric Therapeutics (OPT) provides ethical expertise for scientific and regulatory issues involving the therapeutic and diagnostic initiatives in pediatrics across all of FDA's Centers. The incumbent provides independent review of pediatric research ethics issues and participates in the planning, management, and implementation of pediatric bioethics activities across all of FDA's Centers. Activities will include pediatric research ethics consultation, providing pediatric ethics training to stakeholders within and outside of the agency, and guidance development pertaining to a wide range of pediatric research ethics issues.

**Title 21 Band D GS-15+ equivalent or T38 Physician Tier Coverage/Grade Determinant (See Job Aid Below)**

**Overview**

Open & Closing Date: August 16-30, 2024
Salary Range: \$180,000-\$220,000
<a href="#">Band: D</a>
Occupational Series: 0602
Duty Location: Remote Position
Remote Job: Yes
Telework Eligible: Yes
Travel Required: No
Relocation Expenses Reimbursed: No
Appointment Type: Permanent
Work Schedule: Full Time
Competitive Service: *DO NOT CHANGE
Promotion Potential: Band D
Supervisory Status: n/a
Security Clearance: n/a
Drug Test: n/a
Position Designation: Non-Sensitive/Moderate Risk
Trust Determination Process: Public Trust

### Hiring Path Clarification Text:

You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration. This is a 21st Century Cures Act authority announcement. Traditional federal rules regarding rating, ranking, and veterans' preference do not apply.

### Duties:

Recognized as an agency medical expert in pediatric clinical trial activities and pediatric research ethics. Develops broad and complex regulatory programs. As an expert in pediatrics and ethics, provides information and consultation to individuals, federal agencies, private industry, universities, and/or foreign governments on pediatric ethics issues. Spends most of the time providing expert consultation to the various centers involved in pediatric clinical trial activities. Establishes and maintains communication within the Centers of the Agency to facilitate the exchange of scientific and regulatory information on pediatric research ethics, and to ensure that policy issues are addressed appropriately. Collaborates as a recognized expert with officials and representatives of higher departmental echelons, counterpart government departments or agencies, national and international organizations, the scientific/medical community, and related industries concerning scientific/research programs and activities. Prepares and gives presentations concerning the interpretation and analysis of regulations and statutes to state, local, and foreign governments, subject matter experts, upper levels of management, industry, and academia. Represents the organization before high-level national and international audiences regarding regulatory policies and programs.

As a recognized authority, expert, and leader in pediatrics and bioethics, provides expertise in regulatory review and analysis of programs and operations. Serves as a clinical reviewer of product applications. Analyzes clinical studies and research and performs critical reviews of scientific or technical procedures, methodologies, and protocols, as well as clinical trial design. Reviews the adequacy of protocols and methodology for design of pediatric clinical studies/trials. Analyzes ethical implications and impact on overall scientific activities and priorities, in areas that require extensive interpretation. Develops broad, complex programs or scientific conclusions, opinions, and recommendations that are critical to reviewers of all of FDA Centers, scientific review panels and advisory committees on pre-market approval applications, product development protocols, etc. Develops, writes, and evaluates guidelines concerning information or/and data required in actions submitted to the agency. Develops regulatory standards for the ethical evaluation of the safety, effectiveness, and quality of regulated products/devices.

Possesses specialized skill that is recognized by agency officials, other federal agencies, state, local and foreign governments, regulated industry, and/or professional trade and citizen organizations directly affected by the program/s. In collaboration with senior staff, the incumbent of this position serves as a resource for pediatric research ethics, provides review of

pediatric clinical trial research ethics issues across of the FDA's Centers, provides advice to the Pediatric Review Committee, and participates in the planning, management, and implementation of bioethics activities across all of FDA's centers. Has active work on the protection of pediatric human subjects from research risks through provision of consultation services in the design, review, and monitoring of research protocols. Develops and implements educational programs on contemporary issues in biomedical ethics, especially as they relate to the Agency's mission in clinical research.

As an agency expert in pediatrics, bioethics and the regulatory field, integrates knowledge and experience to resolve problems, modify procedures, and develop and interpret complex policies to meet new and novel conditions. Actions taken and solutions devised cut across other functional areas within the organization. Provides recommendations regarding the implementation of new laws and regulations that influence the mission of the organization. This includes participation in the planning for the initiation and implementation of new policies, systems, procedures, and organizational structures. Leads or serves on task forces and study groups charged with considering problems or directions in an area of expertise. As required, conceives of the mission for such groups, develops proposals for study, and presents the task force's recommendations to senior staff. Leads or serves on committees charged with the review of federal policies and procedures that cross organization lines. Delivers briefings on findings and recommendations. Defends positions, interpretations, and policies before international organizations, government agencies, state and local governments, industry, academia, consumer organizations, and the scientific/medical community. Coordinates and provides interpretation and guidance on overall policy and special issues pertaining to pediatrics and pediatric research ethics.

## Requirements

### Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- The candidate selected for this position will serve under a career or career-conditional appointment within the competitive service.
- Direct Deposit: You will be required to have all federal salary payments electronically deposited into a bank account with a financial institution of your choice.
- FDA participates in e-Verify: All new hires must complete the I-9 form; this information will be processed through e-Verify to determine your employment eligibility. If a discrepancy arises, you must take affirmative steps to resolve the matter.
- Males born after December 31, 1959, must be registered with the Selective Service. Please go to <http://www.sss.gov> for more information.
- One-year probationary period may be required.
- One-year supervisory probationary period may be required.

- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation Requirement: All employees must pass a security investigation. Failing to pass the background check may be grounds for removal or legal action. If hired, you may be subject to additional investigations at a later time. TS/SCI Clearance must be obtained to be eligible for position.
- Certification of Accuracy: All information concerning eligibility and qualification is subject to investigation and verification. False representation may be grounds for non-consideration, non-selection, or appropriate legal action.

### Qualifications

Qualifications will be based on the minimum years of relevant experience, rather than specialized experience, for determining and validating a Title 21 candidate's band. This standard applies across all Title 21 positions. (Please use this [Link](#) for reference).

In order to qualify for the **OPT Physician (Ethicist)**, you must meet the following requirements:

#### Basic Qualification Requirements:

Physician, 0602 Requirements: Must possess a M.D. degree, official transcripts are required. Degree must have been accredited by the Council on Medical Education of the American Medical Association ([external link](#)); Association of American Medical Colleges ([external link](#)); Liaison Committee on Medical Education ([external link](#)); Commission on Osteopathic College Accreditation of the American Osteopathic Association ([external link](#)), or an accrediting body recognized by the U.S. Department of Education ([external link](#)) at the time the degree was obtained.

Pay careful attention to the Qualifications and Education sections to identify vacancies where a transcript is required. Even if you hold a similar position or are a current employee, you are not exempt from transcript requirements.

**TRANSCRIPTS:** Positions which are scientific or technical in nature often have very specific educational requirements. You must submit an official transcript, unofficial transcript, or a list including courses, grades earned, completion dates, and quarter and semester hours earned. Transcripts must identify a degree type, date degree conferred, and identify the major if using education to meet basic degree requirements.

Education must be accredited by an accrediting institution recognized by the [U.S. Department of Education](#) in order for it to be credited towards qualifications. Therefore, provide only the attendance and/or degrees from schools accredited by accrediting institutions recognized by

the U.S. Department of Education.

**If you are using education completed in foreign colleges or universities, see the Foreign Education section below for additional requirements.**

**Electronic Transcript Caution:** If you have obtained your transcripts electronically, the file might contain security measures that could prevent our application system from reading the file. Therefore, you should consider asking the institution to provide the file in a non-secured electronic format. Alternatively, you could scan or take a photo of the printed copy of the transcript. If your uploaded transcript cannot be read by our system, you may receive consideration and credit for the information we can access.

**See the [Application Manager Documentation](#) for tips on submitting your paper-based documents.**

**Foreign Education:** If you are using education completed in foreign colleges or universities to meet the qualification requirements, you must show that the education credentials have been evaluated by a private organization that specializes in interpretation of foreign education programs and such education has been deemed equivalent to that gained in an accredited U.S. education program; or full credit has been given for the courses at a U.S. accredited college or university. **For further information, visit the [U.S. Department of Education website for Foreign Education Evaluation](#).**

**To be acceptable, the foreign credential evaluation must include/describe at a minimum, the following information:** (1) The type of education received by the applicant; (2) The level of education in relation to the U.S. education system, and state that its comparability recommendations follow the general guidelines of the International Evaluation Standards Council; (3) The content of the applicant's educational program earned abroad, and the standard obtained; (4) The status of the awarding foreign school's recognition and legitimacy in its home country's education system; and (5) Any other information of interest such as what the evaluation service did to obtain this information, the qualifications of the evaluator, and any indications as to other problems such as forgery.

**For 0602 positions, you must provide an Educational Commission for Foreign Medical Graduates (ECFMG) certification to meet the foreign education requirement.**

***Note:*** Some positions require the completion of specific courses or a specified number of credit hours. Therefore, the foreign credential evaluation should provide information similar to that of an official transcript, to include a list of the courses taken, quarter and/or semester hours awarded, the cumulative grade point average (GPA), honors received, if any, date degree awarded.

**Applicants can request an evaluation from a member organization of one of the two national associations of credential evaluation services listed below:**

1. [National Association of Credential Evaluation Services](#) (NACES)
2. [Association of International Credentials Evaluators](#) (AICE)

*Credential evaluations are not free, and applicants are responsible for the cost of the selected service.*

***For more information about this requirement, please visit the [U.S. Department of Education website for Foreign Education Evaluation](#).***

#### **Additional Conditions of Employment:**

- **Pre-employment physical required:** No
- **Drug testing required:** No
- **License Required:** No
- **Mobility agreement required:** No
- **Immunization required:** No
- **Bargaining Unit:** 8888
- **Telework eligible position:** Telework is at the discretion of the supervisor.
- **Remote eligible position for highly qualified candidates at the discretion of the supervisor.**
- **Incentives may be authorized;** however, this is contingent upon funds availability. If authorized, certain incentives will require you to sign a service agreement to remain in the Federal government for a period of up to 3 years. Note: This statement does not imply nor guarantee an incentive will be offered and paid. Incentives include the following: moving expenses, recruitment or relocation incentive; student loan repayment, superior qualifications appointment, creditable service for annual leave for prior non-federal work experience or prior uniformed military service, etc.
- **Financial disclosure statement, OGE-450, required:** Please be advised that this position may be subject to FDA's prohibited financial interest regulation and may require the incumbent of this position to divest of certain financial interests. Applicants are advised to seek additional information on this requirement from the hiring official before accepting this position.

This position may require financial disclosure reporting and will be subject to FDA's prohibited financial interest regulation. If you are hired, you may be required to divest of certain financial interests. You are advised to seek additional information on this requirement from the hiring official before accepting any job offers. For more information please visit the FDA Ethics web page: <https://www.fda.gov/about-fda/jobs-and-training-fda/ethics>.

**Additional Information:**

- **Additional selections may be made for similar positions within the commuting area(s) of the locations listed through this vacancy announcement.**
- **If you are serving, or have served in the last 5 years (from 12/01/2023) as an Executive Branch political, Schedule C, or Non-career SES appointee, HHS/FDA may be required to obtain approval by the Office of Personnel Management (OPM) prior to beginning employment.** You can find out if you have held one of these appointment types by looking at your Standard Form 50s in your Electronic Official Personnel Folder (eOPF), in Section 5 where the legal authorities are listed. If you have served or are currently serving, you must provide a copy of your SF-50, Notification of Personnel Action, documenting this appointment. In addition, you will be required to respond to the question in the assessment and certify your responses to the questionnaire. See [Political Appointee FAQ - OPM](#) for more.

***All requirements must be met by the closing date of this announcement **August 30, 2024**; only education and experience gained by this date will be considered. You must continue to meet all requirements throughout the entire hiring process.***

How you will be Evaluated: You will be evaluated for this job based on how well you meet the qualifications above.

This is a Title 21 announcement. Traditional rating and ranking of applications, and veterans' preference does not apply to this vacancy. You will be evaluated against the basic qualifications and if found qualified, you will be referred to the Hiring Manager for consideration.

**If you are referred to the hiring manager for consideration**, you may be further evaluated based on an interview; review of requested work samples, writing samples, most recent performance evaluation(s), or professional references; or results of an oral presentation or work-related test.

**Failure to comply with any of the additional assessment requirements will result in removal from further consideration.**

***Please follow all instructions carefully. Errors or omissions may affect your eligibility.***

**Send applications to: Brenda Harmon ([Brenda.Harmon@fda.hhs.gov](mailto:Brenda.Harmon@fda.hhs.gov)) by COB of announcement closing date**