

**Subpart J—Facility Administration for Nonwaived Testing**

We have determined that COLA's requirements for the specialties of Clinical Cytogenetics and Radiobioassay are equal to or more stringent than the CLIA requirements at §§ 493.1100 through 493.1105.

**Subpart K—Quality System for Nonwaived Testing**

We have determined that COLA's requirements for the specialties of Clinical Cytogenetics and Radiobioassay are equal to or more stringent than the CLIA requirements at §§ 493.1200 through 493.1299.

**Subpart M—Personnel for Nonwaived Testing**

We have determined that COLA's requirements for the specialties of Clinical Cytogenetics and Radiobioassay are equal to or more stringent than the CLIA requirements at §§ 493.1403 through 493.1495 for laboratories that perform moderate and high complexity testing.

**Subpart Q—Inspection**

We have determined that COLA's requirements for the specialties of Clinical Cytogenetics and Radiobioassay are equal to or more stringent than the CLIA requirements at §§ 493.1771 through 493.1780.

**Subpart R—Enforcement Procedures**

We have determined that COLA's requirements for the specialties of Clinical Cytogenetics and Radiobioassay meet the requirements of subpart R to the extent that it applies to accreditation organizations. COLA policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, COLA will deny, suspend, or revoke accreditation in a laboratory accredited by COLA and report that action to us within 30 days. COLA also provides an appeal process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that COLA's laboratory enforcement and appeal policies are equal to or more stringent than the requirements of part 493 subpart R as they apply to accreditation organizations.

**IV. Federal Validation Inspections and Continuing Oversight**

The Federal validation inspections of laboratories accredited by COLA may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is,

complaint inspections). The outcome of those validation inspections, performed by CMS or our agents, or the State survey agencies, will be our principal means for verifying that the laboratories accredited by COLA remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

**V. Removal of Approval as an Accrediting Organization**

CLIA regulations at § 493.575 provide that we may rescind the approval of an accreditation organization, such as that of COLA, before the end of the effective date of approval in certain circumstances. For example, If we determine that COLA has failed to adopt, maintain and enforce requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its monitoring, inspection or enforcement processes, we may impose a probationary period, not to exceed 1 year, in which COLA would be allowed to address any identified issues. Should COLA be unable to address the identified issues within that timeframe, CMS may, in accordance with the applicable regulations, revoke COLA's deemming authority under CLIA.

Should circumstances result in our withdrawal of COLA's approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

**VI. Collection of Information Requirements**

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The requirements associated with the accreditation process for clinical laboratories under the CLIA program, codified in 42 CFR part 493 subpart E, are currently approved by OMB under OMB control number 0938-0686.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Mehmet Oz, having reviewed and approved this document, authorizes Vanessa Garcia, who is the **Federal Register** Liaison, to electronically sign

this document for purposes of publication in the **Federal Register**.

**Vanessa Garcia,**

*Federal Register Liaison, Centers for Medicare & Medicaid Services.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Administration for Children and Families****Statement of Organization, Functions, and Delegations of Authority**

**AGENCY:** Administration for Children and Families, HHS.

**ACTION:** Notice.

**SUMMARY:** Statement of Organizations, Functions, and Delegations of Authority.

The Administration for Children and Families (ACF) has renamed the Office of Child Support Services. This notice changes the name of the office from Office of Child Support Services (OCSS) to Office of Child Support Enforcement (OCSE).

**FOR FURTHER INFORMATION CONTACT:**

Linda Boyer, Deputy Commissioner, Office of Child Support Enforcement, 330 C Street SW, Washington, DC 20201, 202-401-5410.

**SUPPLEMENTARY INFORMATION:** This notice amends Part K of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), Administration for Children and Families (ACF), to be revised as follows: Chapter KF, Office of Child Support Enforcement, as last amended 88 FR 36587, June 5, 2023.

I. Under Chapter KF, Office of Child Support Services, delete KF in its entirety and replace with the following:

**KF.00 Mission:** The Office of Child Support Enforcement (OCSE) advises the Secretary, through the Assistant Secretary for Children and Families/Director of the Office of Child Support Enforcement, on matters pertaining to the child support and access and visitation programs. OCSE provides direction, guidance, and oversight to state and tribal child support programs, the Central Authority for international child support cases, and state access and visitation programs for activities authorized and directed by title IV-D of the Social Security Act and other pertinent legislation. OCSE's core mission is dedicated to establishing paternity and obtaining child support in order to encourage responsible

parenting, family self-sufficiency, and child well-being, and to recognize the essential role of both parents in supporting their children. The national child support program assures that assistance in obtaining support, including financial and medical, is available to children through locating parents, establishing paternity, establishing and modifying support obligations, and monitoring and enforcing those obligations. The specific responsibilities of this Office are to develop, recommend, and issue policies, procedures, and interpretations for state and tribal programs for locating noncustodial parents, establishing paternity, and obtaining child support; develop procedures for review and approval or disapproval of state and tribal plan material; conduct audits of state child support programs; assist states and tribes in establishing adequate reporting procedures and maintaining records for the operation of their child support programs and of amounts collected and disbursed under the child support program and the costs incurred in collecting such amounts; operate the United States and Tribes Central Authority for International Child Support; monitor the access and visitation and fatherhood programs; and provide technical assistance and training to the states and tribes to help them develop effective procedures and systems for services provided by the child support program, including automation, outreach, referral, and case management in partnership with employers, courts, and responsible fatherhood, workforce, and other programs to increase the long-term reliability of support payments available to children. OCSE also operates competitive grant programs for child support in collaboration with several other components within ACF. It also operates the Federal Parent Locator Service (FPLS); certifies to the Secretary of the Treasury amounts of child support obligations that require collection in appropriate instances; transmits to the Secretary of State certifications of arrearages for passport denial; submits reports to Congress, as requested, on activities undertaken relative to the child support program; approves advance data processing planning documents; and reviews, assesses, and inspects planning, design, and operation of state and tribal management information systems. FPLS also assists other federal, state, and local agencies not involved in child support to fulfill their respective missions, save taxpayer dollars, and improve service to the public.

*KF.10 Organization.* The Office of Child Support Enforcement is headed by the Director. The office is organized as follows:

Office of the Director/Deputy Director/Commissioner (KFA)  
Office of Audit (KFAA)  
Office of the Deputy Commissioner (KFB)  
Division of Business and Resource Management (KFB2)  
Division of Customer Communications (KFB3)  
Division of Policy and Training (KFB5)  
Division of Program Innovation (KFB7)  
Division of Regional Operations (KFB8)  
Child Support Services Regional Program Units (KFB8DI-X)  
Division of Federal Systems (KFB9)  
Division of State and Tribal Systems (KFB10)

*KF.20 Functions. Office of the Director and Deputy Director/Commissioner (KFA):* The Director is also the Assistant Secretary for Children and Families and is directly responsible to the Secretary for carrying out OCSE's mission. The Deputy Director/Commissioner has day-to-day operational responsibility for OCSE. The Deputy Director/Commissioner assists the Director in carrying out responsibilities of the Office and provides direction and leadership to the Office of the Deputy Commissioner and the Office of Audit.

The Deputy Director/Commissioner provides leadership and direction to OCSE and is responsible for developing regulations, guidance, and standards for state/tribes to follow in locating absent parents; establishing paternity and support obligations; maintaining relationships with Department officials, other federal departments, state and tribal and local officials, and private organizations and individuals interested in the child support program; coordinating and planning child support program activities to maximize program effectiveness; program outreach, as well as access and visitation programs and advocacy interests; and approving all instructions, policies, and publications. The Deputy Director/Commissioner is also responsible for the operations and maintenance of FPLS, management and financial analysis and strategy development, internal OCSE operations, and compliance with federal laws and policies. The Deputy Director/Commissioner is responsible for collaborating with the Office of Legislative Affairs and Budget and the Government Accountability Office on studies related to the child support program. In addition, the Deputy Director/Commissioner maintains OCSE's Continuity of Operations Plan.

*Office of Audit (KFAA):* The Office of Audit develops, plans, schedules, and conducts periodic audits of child support programs in accordance with audit standards promulgated by the Comptroller General. The office is headed by an Office Director and reports directly to the Commissioner. The Office conducts audits, at least once every 3 years (or more frequently if it is determined that a state has unreliable data or fails to meet the performance standards) to determine the reliability of state financial and statistical data reporting systems used in calculating the performance indicators used as the basis for the payment of performance-based financial incentives to the state. These audits include testing of the data produced by the system to ensure that it is valid, complete, and reliable. The audits also include a review of the state's physical security and access controls.

The Office will also conduct financial audits to determine whether federal and other funds made available to carry out the child support program are being appropriately expended, and properly and fully accounted for. These audits examine collections and disbursements of support payments for proper processing and accounting. In addition, the Office conducts other audits and examinations of program operations, as may be necessary or requested by program officials for the purpose of improving the efficiency, effectiveness, and economy of state, tribal, and local child support activities.

The Office develops consolidated reports for the Commissioner, based on findings, provides specifications for the development of audit regulations and requirements for audits of state programs, and coordinates and maintains effective liaison with the HHS Inspector General's Office and with the Government Accountability Office.

*Office of the Deputy Commissioner (KFB):* The Deputy Commissioner reports to the Deputy Director/Commissioner and assists the Commissioner in carrying out the responsibilities of OCSE. The Deputy Commissioner provides day-to-day supervision and oversight of the Division of Business and Resource Management, Division of Customer Communications, Division of Policy and Training, Division of Program Innovation, Division of Regional Operations, Division of Federal Systems, and Division of State and Tribal Systems. The Deputy Commissioner leads OCSE outreach efforts and builds collaborations with federal, state, tribal, local, and

community agencies to efficiently improve child support services.

The Office of the Deputy Commissioner provides coordination for all OCSE contracts and internal IT systems.

*Division of Business and Resource Management (KFB2):* The Division of Business and Resource Management (DBRM) is responsible for the overall management and operation of OCSE administrative services. The Division is headed by a Division Director who reports directly to the Deputy Commissioner. DBRM leads all efforts related to personnel and the formulation and execution of the discretionary budgets for OCSE program funds and federal administration funds. DBRM develops, implements, and manages all personnel activities; provides guidance on all labor and employee relations; coordinates performance management, employee engagement, and recognition; provides training and technical assistance on business administrative services; manages OCSE-controlled space, facilities, assets, and messenger services; and provides for health and safety. DBRM also serves as the funding authority for all OCSE acquisitions and grant opportunities, procures all goods and services, and coordinates all travel and conference management activities.

*Division of Customer Communications (KFB3):* A Division Director leads the Division of Customer Communications (DCC) and reports to the Deputy Commissioner. The Division has two branches. The *Customer Service* branch responds to requests for information on specific child support cases from custodial and noncustodial parents, the White House, members of Congress, Office of Inspector General, state agencies, reciprocating countries, and various interest groups. The *Program Communications* branch plans, designs, and executes public outreach and communications campaigns to convey information about the child support program and engage with child support stakeholders. The branch is responsible for providing guidance on strategies and approaches to improve public understanding of and access to OCSE programs and policies, developing and publishing informational materials on the OCSE website, and engaging with our stakeholders through social media. With these information channels, DCC serves as a focal point for consistent, clear, and accurate program communication.

*Division of Policy and Training (KFB5):* The Division of Policy and Training (DPT) proposes and implements national policy for the child support program and provides policy

guidance and interpretations to states and tribes in developing and operating their programs according to federal law. DPT is headed by a Division Director who directly reports to the Deputy Commissioner and is supported by the *Policy* Branch and the *Training* Branch. The *Policy* Branch develops legislative proposals and regulations to implement new legislation, court decisions, or directives from higher authority, and provides comments on pending legislative proposals. It develops new state plan preprint requirements and procedures for review and approval by the Division of Regional Operations. Additionally, the *Policy* Branch reviews the state plan submittals and prepares justifications for plan disapproval action. DPT coordinates with the Office of General Counsel on pending departmental appeals and collaborates with ACF on audit resolution. DPT also implements Central Authority activities for international support enforcement and functions as the U.S. Central Authority for international support enforcement. The *Training* Branch provides national direction and leadership for OCSE training activities to increase child support program effectiveness at federal, state, and tribal levels; coordinates child support program training activities; and provides logistical support for child support training events, meetings, and conferences.

*Division of Program Innovation (KFB7):* The Division of Program Innovation (DPI) develops, evaluates, and refines new strategies to improve child support program effectiveness and disseminates information about promising and evidence-based practice. The Division is headed by a Division Director who reports directly to the Deputy Commissioner. DPI manages research and demonstration projects, including Section 1115 grants and waivers and Special Improvement Project grants, and promotes program evaluation at the state and local levels. DPI also implements special projects of regional or national significance, pilots new child support approaches, and administers the Access and Visitation Grant Program.

*The Division of Regional Operations (KFB8):* The Division of Regional Operations (DRO) provides direct oversight of all child support Regional Program Unit operations, including ensuring customer-focused partnerships to child support programs and services and implementation of child support regional operations, policies, budgets, and program compliance of all 10 regions. This includes oversight of Regional Program Units providing

technical assistance and support to state and tribal child support agencies. The Division is headed by a Director, who reports directly to the Deputy Commissioner. DRO provides management and oversight of the Regions through coordinating activities between Central Office Divisions and the Regional Program Units. The Division provides information to improve public understanding of and across to OCSE programs and policies. The Division is responsible for providing oversight of all regional representation at conferences and meetings both within the child support community and other collaborative programs and partners. The Division is also responsible for the management, receipt, review, and analysis of public inquiries and the preparation of formal (both written and electronic) responses to external inquiries for child support program information and assistance in obtaining child support services.

*Child Support Enforcement Regional Program Units (KFB8DI-X):* Each OCSE Regional Program Unit is headed by the OCSE Regional Program Manager who reports to the Director of the Division of Regional Operations. The OCSE Regional Program Manager, through regional staff and in collaboration with program stakeholders, is responsible for (1) providing program and technical administration of the ACF entitlement and discretionary programs related to OCSE; (2) collaborating with the ACF central office, states, tribes, and other external programs and grantees on all significant program and policy matters; (3) providing technical assistance and training to entities responsible for administering OCSE programs to resolve identified problems; (4) ensuring that appropriate procedures and practices are adopted; (5) working with appropriate state, tribal, and local offices to develop innovative practices to support family self-sufficiency; and (6) monitoring the programs to ensure their efficiency and effectiveness, and ensuring that these entities conform to federal laws, regulations, policies, and procedures governing the programs.

*Division of Federal Systems (KFB9):* The Division of Federal Systems (DFS) is responsible for the design, development, deployment, maintenance, and implementation of FPLS. The Division is headed by a Division Director who directly reports to the Deputy Commissioner. FPLS is made up of a group of data sharing, collection, and program systems, such as the federal tax refund offset program, that helps OCSE support the core mission of the child support program and helps prevent improper payments

in state and federal benefit programs through NDNH data matching. DFS provides states with data to help them locate parents, establish fair and equitable child support obligations, process income withholding and payments, collect and enforce past-due child support, and communicate effectively and efficiently. DFS provides outreach, technical support, and training to child support agencies, employers, insurers, financial institutions, and other private and government partners to ensure that the FPLS systems are used to their maximum benefit.

DFS is responsible for automation of data and timeliness of transactions. Other responsibilities include, but are not limited to, oversight of collaborations with the Social Security Administration (SSA) on technical aspects of their use of OCSE's data and OCSE's use of SSA data center resources; conduct analyses and feasibility assessments; develop requirements; and design, develop, and implement system enhancements to increase efficiencies and support users of FPLS information. DFS also ensures that all IT projects are managed according to OMB/HHS/ACF standards for architecture, capital planning, security, and privacy, and fall within tolerances for acceptance.

Additionally, DFS provides guidance, analysis, technical assistance, and oversight to state and tribal child support programs regarding performance measurement; statistical, policy, and program analysis; synthesis and dissemination of data sets to inform the program; and application of emerging technologies, such as business intelligence and data analytics to improve and enhance the effectiveness of programs and service. DFS is also responsible for collection, compilation, analysis, and dissemination of state and tribal data to Congress and the general public. The Division also provides statistical and budgeting support in coordination with other divisions. DFS is responsible for promoting public access and understanding of data; managing academic/research projects; and providing support for researchers. DFS provides technical assistance to states in developing their self-assessment capabilities and implementing the annual reporting requirements contained in the Personal Responsibility and Work Opportunity Reconciliation Act of 1996.

*Division of State and Tribal Systems (KFB10):* The Division of State and Tribal Systems (DSTS) reviews, analyzes, and approves/disapproves state and tribal requests for Federal

Financial Participation for automated systems development and operations activities that support the child support program. DSTS is headed by a Division Director who directly reports to the Deputy Commissioner. DSTS provides assistance to states and tribes in developing or modifying automation plans to conform to federal requirements. DSTS monitors approved state and tribal systems development activities; certifies state-wide automated systems; and conducts periodic reviews to assure state and tribal compliance with regulatory requirements applicable to automated systems supported by Federal Financial Participation. DSTS provides guidance to states and tribes on functional requirements for these automated information systems, and works with federal, state, local, and tribal health and human services agencies to foster and promote interoperability and collaboration across the automated systems that support their programs. The Division promotes interstate and tribal transfer of existing automated systems and provides assistance and guidance to improve ACF's programs through the use of automated systems and technology. It provides development support and guidance to tribes on the installation, implementation, and maintenance of the Model Tribal System.

**II. Continuation of Policy.** Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to organizational components affected by this notice within ACF, heretofore issued and in effect on this date of this reorganization are continued in full force and effect.

**III. Delegation of Authority.** All delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

**IV. Funds, Personnel, and Equipment.** Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies, and other resources.

This reorganization became effective upon completion of a Congressional notification period.

**Robert F. Kennedy, Jr.,**

*Secretary, Department of Health and Human Services.*

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**BILLING CODE 4184-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2025-P-1304]

### Determination That EFFEXOR XR (Venlafaxine Hydrochloride) Extended-Release Capsule, 100 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined that EFFEXOR XR (venlafaxine hydrochloride) extended-release capsule, 100 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

#### FOR FURTHER INFORMATION CONTACT:

Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-8363, *Stacy.Kane@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

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