

**III. Evaluation of Deeming Authority Request**

In the September 23, 2019 **Federal Register**, we published TCT’s initial application for recognition as an accreditation organization for HIT (84 FR 49736). On September 28, 2020, we published notification of their approval as such an organization, effective October 1, 2020 through October 1, 2024 (85 FR 60799). TCT has since submitted all the necessary materials to enable us to make a determination concerning its request for continued recognition of its HIT accreditation program. This application was determined to be complete on March 2, 2024. Under section 1834(u)(5) of the Act and 42 CFR 488.1010 (Application and re-application procedures for national home infusion therapy accrediting organizations), our review and evaluation of TCT will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of TCT’s standards for HIT as compared with CMS’ HIT requirements for participation in the Medicare program.
- TCT’s survey process to determine the following:

- ++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

- ++ The comparability of TCT’s to CMS’ standards and processes, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

- ++ TCT’s processes and procedures for monitoring a HIT supplier found out of compliance with TCT’s program requirements.

- ++ TCT’s capacity to report deficiencies to the surveyed facilities and respond to the facility’s plan of correction in a timely manner.

- ++ TCT’s capacity to provide CMS with electronic data and reports necessary for effective assessment and

interpretation of the organization’s survey process.

- ++ The adequacy of TCT’s staff and other resources, and its financial viability.

- ++ TCT’s capacity to adequately fund required surveys.

- ++ TCT’s policies with respect to whether surveys are announced or unannounced, to ensure that surveys are unannounced.

- ++ TCT’s agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS may require (including corrective action plans).

- ++ TCT’s policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys, audits or participate in accreditation decisions.

- ++ TCT’s agreement or policies for voluntary and involuntary termination of HIT suppliers.

- ++ TCT’s agreement or policies for voluntary and involuntary termination of the HIT AO program.

**IV. 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 under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

**V. Response to Comments**

Because of the large number of public comments, we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will

respond to the comments in the preamble to that document.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

**Trenesha Fultz-Mimms**,  
*Federal Register Liaison, Centers for Medicare & Medicaid Services.*

[FR Doc. 2024–09172 Filed 4–26–24; 8:45 am]

**BILLING CODE 4120–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[CMS–9148–N]

**Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—January through March 2024**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice.

**SUMMARY:** This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published in the 3-month period, relating to the Medicare and Medicaid programs and other programs administered by CMS.

**FOR FURTHER INFORMATION CONTACT:** It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone No.
I CMS Manual Instructions .....	Ismael Torres .....	(410) 786–1864
II Regulation Documents Published in the <b>Federal Register</b> .....	Terri Plumb .....	(410) 786–4481
III CMS Rulings .....	Tiffany Lafferty .....	(410)786–7548
IV Medicare National Coverage Determinations .....	Wanda Belle, MPA .....	(410) 786–7491
V FDA-Approved Category B IDEs .....	John Manlove .....	(410) 786–6877
VI Collections of Information .....	William Parham .....	(410) 786–4669
VII Medicare—Approved Carotid Stent Facilities .....	Sarah Fulton, MHS .....	(410) 786–2749
VIII American College of Cardiology-National Cardiovascular Data Registry Sites .....	Sarah Fulton, MHS .....	(410) 786–2749
IX Medicare’s Active Coverage-Related Guidance Documents .....	Lori Ashby, MA .....	(410) 786–6322
X One-time Notices Regarding National Coverage Provisions .....	JoAnna Baldwin, MS .....	(410) 786–7205
XI National Oncologic Positron Emission Tomography Registry Sites .....	David Dolan, MBA .....	(410) 786–3365
XII Medicare—Approved Ventricular Assist Device (Destination Therapy) Facilities .....	David Dolan, MBA .....	(410) 786–3365
XIII Medicare—Approved Lung Volume Reduction Surgery Facilities .....	Sarah Fulton, MHS .....	(410) 786–2749
XIV Medicare—Approved Bariatric Surgery Facilities .....	Sarah Fulton, MHS .....	(410) 786–2749

Addenda	Contact	Phone No.
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials .....	David Dolan, MBA .....	(410) 786-3365
All Other Information .....	Annette Brewer .....	(410) 786-6580

**SUPPLEMENTARY INFORMATION:****I. Background**

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance. Administration and oversight of these programs involves the following: (1) furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

**II. Format for the Quarterly Issuance Notices**

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and “real time” accessibility. In addition, many of the websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the need to check the website, as notification of updates is automatic and

sent to the subscriber as they occur. If assessing a website proves to be difficult, the contact person listed can provide information.

**III. How to Use the Notice**

This notice is organized into 15 addenda so that a reader may access the subjects published during the quarter covered by the notice to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals should view the manuals at <http://www.cms.gov/manuals>.

The Director of the Office of Strategic Operations and Regulatory Affairs of the Centers for Medicare & Medicaid Services (CMS), Kathleen Cantwell, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the **Federal Register Liaison**, to electronically sign this document for purposes of publication in the **Federal Register**.

**Trenesha Fultz-Mimms,**  
*Federal Register Liaison, Department of Health and Human Services.*

**BILLING CODE 4120-01-P**

### Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: May 12, 2023 (88 FR 30752), August 4, 2023 (88 FR 51814), October 26, 2023 (88 FR 73591) and January 30, 2024 (89 FR 5897). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

### Addendum I: Medicare and Medicaid Manual Instructions (January through March 2024)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

#### How to Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: <http://cms.gov/manuals>.

#### How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at <http://www.gpo.gov/libraries/>

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government

publications, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual Updates to Medicare Benefit Policy Manual and Medicare Claims Processing Manual for Marriage and Family Therapists (MFTs) and Mental Health Counselors (MHCs) (CMS-Pub. 100-02) Transmittal No. 12448.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual.

#### Fee-For Service Transmittal Numbers

**Please Note:** Beginning Friday, March 20, 2020, there will be the following change regarding the Advance Notice of Instructions due to a CMS internal process change. Fee-For Service Transmittal Numbers will no longer be determined by Publication. The Transmittal numbers will be issued by a single numerical sequence beginning with Transmittal Number 10000.

For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at [www.cms.gov/Manuals](http://www.cms.gov/Manuals).

Transmittal Number	Manual/Subject/Publication Number
<b>Medicare General Information (CMS-Pub. 100-01)</b>	
12531	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
<b>Medicare Benefit Policy (CMS-Pub. 100-02)</b>	
12448	Updates to Medicare Benefit Policy Manual and Medicare Claims Processing Manual for Marriage and Family Therapists (MFTs) and Mental Health Counselors (MHCs)
12497	Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation (PR/CR/ICR) Expansion of Supervising Practitioners
12532	Update to Pub. 100-02 Medicare Benefit Policy Manual, Chapter 15, Section 110.8 Durable Medical Equipment Prosthetics Orthotics and Supplies (DMEPOS) Benefit Category Determinations and Add Section 145 Lymphedema Compression Treatment Items
<b>Medicare National Coverage Determination (CMS-Pub. 100-03)</b>	
	None
<b>Medicare Claims Processing (CMS-Pub. 100-04)</b>	
12439	January 2024 Update of the Ambulatory Surgical Center (ASC) Payment System

12442	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) – April 2024
12443	Clinical Laboratory Fee Schedule – Medicare Travel Allowance Fees for Collection of Specimens and New Updates for 2024
12446	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12448	Updates to Medicare Benefit Policy Manual and Medicare Claims Processing Manual for Marriage and Family Therapists (MFTs) and Mental Health Counselors (MHCs)
12449	April 2024 Quarterly Update to Healthcare Common Procedure Coding System (HCPCS) Codes Used for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Enforcement
12451	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12452	Implementation of System Edits for Direct Graduate Medical Education (DGME) and Kidney Acquisition Pass-Thru Amount Fields of the Provider Specific File (PSF)
12453	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12455	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12456	New Physician Specialty Code for Epileptologists
12462	Update to the Payment for Grandfathered Tribal Federally Qualified Health Centers (FQHCs) for Calendar Year (CY) 2024
12472	File Conversions Related to the Spanish Translation of the Healthcare Common Procedure Coding System (HCPCS) Descriptions
12473	Indian Health Services (IHS) Hospital Payment Rates for Calendar Year 2024
12474	Quarterly Update to the End-Stage Renal Disease Prospective Payment System (ESRD PPS)
12475	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12476	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12491	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12494	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12497	Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation (PR/CR/ICR) Expansion of Supervising Practitioners
12498	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code (CARC), Medicare Remit Easy Print (MREP) and PC Print Update
12499	Combined Common Edits/Enhancements Modules (CCEM) Code Set Update
12500	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
12501	Quarterly Update to the Medicare Physician Fee Schedule Database (MPFSDB) – April 2024 Update
12503	July 2024 Healthcare Common Procedure Coding System (HCPCS) Quarterly Update Reminder
12504	Home Infusion Therapy (HIT) Payment Rates and Instructions for Retrieving the January 2024 Home Infusion Therapy (HIT) Services Payment Rates Through the CMS Mainframe Telecommunications System
12511	Manual Updates to Chapters 1 and 17 of the Medicare Claims Processing Manual to Reflect Policies Finalized in the Calendar Year (CY) 2024 Physician Fee Schedule Final Rule

12517	Update of Internet Only Manual (IOM), Pub. 100-04, Chapter 8 - Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims
12519	Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment
12521	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12522	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12527	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12530	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12535	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12540	Changes to the Laboratory National Coverage Determination (NCD) Edit Software for July 2024
12547	July 2024 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files
12551	April 2024 Integrated Outpatient Code Editor (I/OCE) Specifications Version 25.1
12552	April 2024 Update of the Hospital Outpatient Prospective Payment System (OPPS)
12553	April Quarterly Update for 2024 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule
<b>Medicare Secondary Payer (CMS-Pub. 100-05)</b>	
12438	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity of Instruction
<b>Medicare Financial Management (CMS-Pub. 100-06)</b>	
12456	New Physician Specialty Code for Epileptologists Claims Processing Timeliness - All Claims Part E - Interest Payment Data Classification of Claims for Counting Physician/Limited License Physician Specialty Codes Exhibit
12457	Notice of New Interest Rate for Medicare Overpayments and Underpayments -2nd Quarter Notification for FY 2024
12492	The Fiscal Intermediary Shared System (FISS) Submission of Copybook Files to the Provider and Statistical Reimbursement (PS&R) System
12507	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12509	Updating Chapter 3, Sections 200.5 - 200.8, Limitation on Recoupment; Medicare Overpayments Manual Administrative Law Judge (ALJ) Third level and Subsequent Levels of Administrative Appeals Actions on a Valid Notification for the ALJ or Subsequent Level Appeal Request Remanded back to the QIC from the ALJ Actions to Take After the ALJ or Subsequent Level Appeal Decision The Revised Overpayment Letter for ALJ and Subsequent Decisions Obligation to Pay Interest on Underpayments 935 Interest Calculation Assessment of 935 Interest Interest Rate and Calculation Periods on Recouped Funds for the Purposes of Paying 935 Interest Calculations for Each 30-Day Period at the ALJ or Subsequent Level Decision Timeframes when Calculation the 935 Interest Computing 935 Interest on Favorable Decisions from the ALJ and Subsequent Levels Tracking and Report the 935 Interest Payments
<b>Medicare State Operations Manual (CMS-Pub. 100-07)</b>	

217	Revisions to the State Operating Manual (SOM) Chapter 2: Community Mental Health Center (CMHC)
218	Revisions to the State Operating Manual (SOM), Appendix F-Community Mental Health Centers
<b>Medicare Program Integrity (CMS-Pub. 100-08)</b>	
12458	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12469	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12478	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12505	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12512	Documentation Requirements for Refillable Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)
12514	Fourth Policy Change Request (CR) Regarding Implementation of the Provider Enrollment, Chain and Ownership System (PECOS) 2.0
12515	Updates of Chapter 4, Chapter 8, and Exhibits in Publication (Pub.) 100-08, Including Prioritization and Payment Suspension Language Guidance Investigations CMS Approval Terminating the Payment Suspension DME Payment Suspensions (MACs and UPICs Non-DME National Payment Suspensions (MACs and UPICs)
12520	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12524	Stay of Enrollment Revalidation Solicitations Non-Responses to Revalidation and Extension Requests Receipt and Processing of Revalidation Applications
12528	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12541	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12542	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12543	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12544	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instruction
12545	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
<b>Medicare Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)</b>	
	None
<b>Medicare Quality Improvement Organization (CMS- Pub. 100-10)</b>	
	None
<b>Medicare Program of All-Inclusive Care for the Elderly (CMS- Pub. 100-11)</b>	
	None
<b>Medicare End Stage Renal Disease Network Organizations (CMS Pub 100-14)</b>	
	None
<b>Medicaid Program Integrity Disease Network Organizations (CMS Pub 100-15)</b>	
	None
<b>Medicare Managed Care (CMS-Pub. 100-16)</b>	

130	Update to Section 20.2.1 and 20.2.5-20.2.7 on the definitions of dual eligible special needs plans (D-SNPs) and additional requirements for certain D-SNPs General Definitions Eligibility Definitions D-SNP Definitions Definition of a D-SNP Definition of a FIDE SNP Definition of HIDE SNP Coordination-only D-SNPs Applicable Integrated Plan Additional Requirements for Certain D-SNPs Application of Frailty Adjustment for FIDE SNPs Medicaid Carve-Outs and FIDE SNP and HIDE SNP Status Benefit Flexibility Eligibility Requirements Characteristics and Categories of Flexible Supplemental benefits Benefit Flexibility Approval Process State D-SNP-only Contracts Limiting Certain MA Contracts to D-SNPs State Notification to CMS Integrated Materials
<b>Medicare Business Partners Systems Security (CMS-Pub. 100-17)</b>	
	None
<b>Medicare Prescription Drug Benefit (CMS-Pub. 100-18)</b>	
	None
<b>Demonstrations (CMS-Pub. 100-19)</b>	
12412	Accountable Care Organization (ACO) REACH PY2023 Part Five – Implementation
12459	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
12465	Enhancing Oncology Model (EOM) Monthly Enhanced Oncology Services (MEOS) Prohibited Codes Updates
12480	Payment of M0010 Enhancing Oncology Model (EOM) Monthly Enhanced Oncology Services (MEOS) Claims for Beneficiaries Receiving Care in an Inpatient Setting
12496	Making Care Primary (MCP) Model Implementation
12536	Guiding an Improved Dementia Experience (GUIDE) Model Implementation
12538	Making Care Primary (MCP) Model Implementation
<b>One Time Notification (CMS-Pub. 100-20)</b>	
12440	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs)--April 2024 Update--CR 2 of 2
12441	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs)--April 2024 Update--CR 1 of 2
12444	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs)--January 2024 Update
12447	Modifications to the Automated Duplicate Primary Payer (DPP) Process
12450	Updating Fiscal Intermediary Shared System (FISS) Editing for Practice Locations to Bypass Non-OPPS Provider
12454	System Updates to Lump Sum Utility for Addition of Wage Index Fields
12463	Fiscal Intermediary Shared System (FISS) - Delete Obsolete Reason Codes - Part 3
12464	Fiscal Intermediary Shared System (FISS) - Delete Obsolete Reason Codes – Part
12470	Issued to a specific audience, not posted to Internet/Intranet due to a

	Confidentiality of Instruction
12481	User Enhancement Change Request (UECR): ViPS Medicare System (VMS) - Add System Auditing Function Expert (SAFE) system to Online Documentation System (OLDS) for Error Messages
12482	User Enhancement Change Request (UECR): ViPS Medicare System (VMS) - Create Multi-line Add Functionality and View Only Mode to the Message File (MSSG)
12483	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12484	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12485	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12486	User Enhancement Change Request (UECR): ViPS Medicare System (VMS) – FIND Command for SuperOp Value Set Definition Screen
12487	User Enhancement Change Request (UECR): ViPS Medicare System (VMS) – FIND Command for Super Definition Screen
12488	User Enhancement Change Request (UECR): ViPS Medicare System (VMS) – Update Electronic Funds Transfer (EFT) Process when a Change of Information (COI) Is Received
12489	User Enhancement Change Request (UECR): ViPS Medicare System (VMS) – Update Paging on Claim/Pricing Inquiry Split Screen
12490	User Enhancement Change Request (UECR): ViPS Medicare System (VMS)- Update Suppression Adjustment Force Code Processing
12493	International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs)–July 2024 Update
12506	User Enhancement Change Request (UECR): New Multi- Carrier System (MCS) Inquiry Search Screen Using a Procedure Code to Display an Associated Edit or Audit
12508	Appropriate Use Criteria for Advanced Diagnostic Imaging Policy Update in the Calendar Year 2024 Physician Fee Schedule Final Rule
12510	User Enhancement Change Request (UECR): ViPS Medicare System (VMS) - Cancellation Process Phase 2
12513	Change Request (CR) to Implement the Medicare Program Final Action: Treatment of Medicare Part C Days in the Calculation of a Hospital’s Medicare Disproportionate Patient Percentage
12518	Report of Hospice Election for Part D (Response File)
12537	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
12539	Implementation to Expand Monetary Amount Fields Related to Billing and Payment to Accommodate 10-Digits in Length (\$99,999,999.99) - Phase 3
12549	Fiscal Intermediary Shared System (FISS) User Enhancement Change Request (UECR) - Expiration of a Unique Tracking Number (UTN) on the Prior Authorization (PA) Tracking File
<b>Medicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)</b>	
	None
<b>State Payment of Medicare Premiums (CMS-Pub.100-24)</b>	
	None
<b>Information Security Acceptable Risk Safeguards (CMS-Pub. 100-25)</b>	
	None

For questions or additional information, contact Ismael Torres (410-786-1864).

### **Addendum II: Regulation Documents Published in the Federal Register (January through March 2024)**

#### Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. To purchase individual copies or subscribe to the **Federal Register**, contact GPO at [www.gpo.gov/fdsys](http://www.gpo.gov/fdsys). When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through GPO Access. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at <http://www.gpoaccess.gov/fr/index.html>. The following website <http://www.archives.gov/federal-register/> provides information on how to access electronic editions, printed editions, and reference copies.

For questions or additional information, contact Terri Plumb (410-786-4481).

### **Addendum III: CMS Rulings (January through March 2024)**

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings>.

For questions or additional information, contact Tiffany Lafferty (410-786-7548).

### **Addendum IV: Medicare National Coverage Determinations (January through March 2024)**

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on

program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. For the purposes of this quarterly notice, there were no specific updates to national coverage determinations (NCDs), or reconsiderations of completed NCDs published in the 3-month period. This information is available at: [www.cms.gov/medicare-coverage-database/](http://www.cms.gov/medicare-coverage-database/).

For questions or additional information, contact Wanda Belle, MPA (410-786-7491).

**Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (January through March 2024)**  
(Inclusion of this addenda is under discussion internally.)

**Addendum VI: Approval Numbers for Collections of Information (January through March 2024)**

All approval numbers are available to the public at [Reginfo.gov](http://Reginfo.gov). Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain).

For questions or additional information, contact William Parham (410-786-4669).

**Addendum VII: Medicare-Approved Carotid Stent Facilities (January through March 2024)**

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at:

<http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage>

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	Provider Number	Date Approved	State
The following facility has editorial changes (in bold).			

Facility	Provider Number	Date Approved	State
<b>FROM: Saint John's Hospital and Health Center</b> <b>TO: Saint John's Health Center</b> 2121 Santa Monica Boulevard Santa Monica, CA 90404	050290	02/09/2007	Ca

**Addendum VIII: American College of Cardiology's National Cardiovascular Data Registry Sites (January through March 2024)**

The initial data collection requirement through the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) has served to develop and improve the evidence base for the use of ICDs in certain Medicare beneficiaries. The data collection requirement ended with the posting of the final decision memo for Implantable Cardioverter Defibrillators on February 15, 2018.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

**Addendum IX: Active CMS Coverage-Related Guidance Documents (January through March 2024)**

CMS issued a guidance document on November 20, 2014 titled "Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document". Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS's implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at <http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27>.

CMS published three proposed guidance documents on June 22, 2023 to provide a framework for more predictable and transparent evidence development and encourage innovation and accelerate beneficiary access to new items and services. The documents are available at:

<https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=35&docTypeId=1&sortBy=title&bc=16>

<https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=34&docTypeId=1&sortBy=title&bc=16>

<https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=33&docTypeId=1&sortBy=title&bc=16>

For questions or additional information, contact Lori Ashby, MA (410 786 6322).

**Addendum X:**

**List of Special One-Time Notices Regarding National Coverage Provisions (January through March 2024)**

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at <http://www.cms.gov>.

For questions or additional information, contact JoAnna Baldwin, MS (410-786 7205).

**Addendum XI: National Oncologic PET Registry (NOPR) (January through March 2024)**

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography (PET)** scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies.

Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at <http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage>.

For questions or additional information, contact David Dolan, MBA (410-786-3365).

**Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (January through March 2024)**

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, we are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at

<http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage>.

For questions or additional information, contact David Dolan, MBA, (410-786-3365).

Facility	Provider Number	Date of Initial Certification	Date of Re-certification	State
<b>The following facility is a new listing.</b>				
Virtua Our Lady of Lourdes Medical Center 1600 Haddon Avenue Camden, NJ 08103  Other information: DNV ID #: C644464  Previous Re-certification Dates: n/a	310029	01/03/2023		NJ
<b>The following facilities have editorial changes (in bold).</b>				
Inova Fairfax Hospital 3300 Gallows Road Falls Church, VA 22042  Other information: Joint Commission ID #: 6351  Previous Re-certification Dates: 12/09/2008; 03/22/2011; 05/01/2013; 06/09/2015; 07/25/2017; 9/25/2019; 11/17/2021	490063	12/09/2008	<b>10/28/2023</b>	VA
St. Vincent Hospital and Health Care Services, Inc. 2001 West 86th Street Indianapolis, IN 46260  Other information: Joint Commission ID #: 7178  Previous Re-certification Dates: 12/16/2008; 05/17/2011; 06/25/2013; 05/19/2015; 06/13/2017; 7/31/2019; 11/06/2021	150084	12/16/2008	<b>11/08/2023</b>	IN



MultiCare Tacoma General Hospital 315 Martin Luther King Jr. Way Tacoma, WA 98338  Other information: DNV ID #: C565359  Previous Re-certification Dates: 11/03/2010; 11/14/2012; 11/18/2014; 12/06/2016; 02/09/2021	500129	11/03/2010	<b>02/09/2024</b>	WA
Loyola University Medical Center 2160 South First Avenue Maywood, IL 60153  Other information: Joint Commission ID #: 7288  Previous Re-certification Dates: 05/10/2011; 04/16/2013; 03/17/2015; 05/09/2017; 6/26/2019; 11/17/2021	140276	01/30/2004	<b>12/01/2023</b>	IL
Mayo Clinic Arizona 5777 East Mayo Boulevard Phoenix, AZ 85054  Other information: Joint Commission ID #: 261796  Previous Re-certification Dates: 01/27/2009; 04/29/2011; 03/20/2013; 03/24/2015; 05/19/2017; 8/14/2019; 10/30/2021	030103	01/27/2009	<b>11/29/2023</b>	AZ
St. Luke's University Hospital 801 Ostrum Street Bethlehem, PA 18015  Other information: Joint Commission ID #: 6024  Previous Re-certification Dates: 12/18/2014; 01/24/2017; 03/06/2019; 10/30/2021	390049	12/18/2014	<b>12/06/2023</b>	PA

Baystate Medical Center 759 Chestnut Street Springfield, MA 01199  Other information: Joint Commission ID #: 2768  Previous Re-certification Dates: 07/18/2017; 9/11/2019; 12/04/2021	220077	07/18/2017	<b>12/20/2023</b>	MA
Intermountain Healthcare Health Services Inc. 5121 South Cottonwood Street Murray, UT 84107  Other information: Joint Commission ID #: 9540  Previous Re-certification Dates: 10/31/2008; 12/07/2010; 12/11/2012; 12/16/2014; 01/24/2017; 3/13/2019; 11/11/2021	460010	10/31/2008	<b>11/15/2023</b>	UT
UCSF Medical Center 505 Parnassus Avenue San Francisco, CA 94143  Other information: Joint Commission ID #: 10095  Previous Re-certification Dates: 09/19/2012; 11/04/2014; 12/06/2016; 1/30/2019; 11/18/2021	050454	09/19/2012	<b>12/13/2023</b>	CA
University of Washington Medical Center 1959 Northeast Pacific Street, Box 356151 Seattle, WA 98195-6151  Other information: Joint Commission ID #: 9626  Previous Re-certification Dates: 02/10/2009; 10/18/2011; 11/22/2013; 12/08/2015; 12/05/2017; 11/20/2019; 01/26/2022	500008	02/10/2009	<b>01/24/2024</b>	WA

Hartford Hospital 80 Seymour Street Hartford, CT 06102-5037  Other information: Joint Commission ID #: 2649  Previous Re-certification Dates: 03/31/2009; 11/16/2011; 10/22/2013; 10/20/2015; 11/14/2017; 12/10/2019; 12/15/2021	070025	03/31/2009	<b>01/05/2024</b>	CT
Hackensack University Medical Center 30 Prospect Avenue Hackensack, NJ 07601  Other information: Joint Commission ID #: 5934  Previous Re-certification Dates: 10/20/2015; 09/19/2017; 10/4/2019; 12/15/2021	310001	10/20/2015	<b>01/18/2024</b>	NJ
Mayo Clinic Florida 4500 San Pablo Road Jacksonville, FL 32224  Other information: Joint Commission ID #: 369946  Previous Re-certification Dates: 03/17/2009; 10/19/2011; 09/24/2013; 09/15/2015; 10/03/2017; 11/6/2019; 01/15/2022	100151	03/17/2009	<b>02/02/2024</b>	FL

**Addendum XIII: Lung Volume Reduction Surgery (LVRS)  
(January through March 2024)**

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.

Only the first two types are in the list. For the purposes of this quarterly notice, there are no additions and deletions to a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. This information is available at [www.cms.gov/MedicareApprovedFacilities/LVRS/list.asp#TopOfPage](http://www.cms.gov/MedicareApprovedFacilities/LVRS/list.asp#TopOfPage).

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

**Addendum XIV: Medicare-Approved Bariatric Surgery Facilities  
(January through March 2024)**

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS' minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at [www.cms.gov/MedicareApprovedFacilities/BSF/list.asp#TopOfPage](http://www.cms.gov/MedicareApprovedFacilities/BSF/list.asp#TopOfPage).

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

**Addendum XV: FDG-PET for Dementia and Neurodegenerative  
Diseases Clinical Trials (January through March 2024)**

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our website at [www.cms.gov/MedicareApprovedFacilities/PETDT/list.asp#TopOfPage](http://www.cms.gov/MedicareApprovedFacilities/PETDT/list.asp#TopOfPage).

For questions or additional information, contact David Dolan, MBA (410-786-3365).

[FR Doc. 2024–09165 Filed 4–26–24; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2010–N–0155]

#### Veterinary Feed Directive Regulation Questions and Answers; Small Entity Compliance Guide; Guidance for Industry (Revised); Availability

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry (GFI) #120 entitled “Veterinary Feed Directive Regulation Questions and Answers.” This revised guidance document will aid industry in complying with the requirements of the veterinary feed directive (VFD) regulation.

**DATES:** The announcement of the guidance is published in the **Federal Register** on April 29, 2024.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

**Instructions:** All submissions received must include the Docket No. FDA–2010–N–0155 for “Veterinary Feed Directive Regulation Questions and Answers.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents and the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the

docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

#### FOR FURTHER INFORMATION CONTACT:

Dragan Momcilovic, Center for Veterinary Medicine (HFV–241), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5944, [Dragan.Momcilovic@fda.hhs.gov](mailto:Dragan.Momcilovic@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of September 30, 2015 (80 FR 58602), FDA announced the availability of GFI #120 entitled “Veterinary Feed Directive Regulation Questions and Answers” to assist industry in complying with the VFD regulation in 21 CFR part 558. This guidance also serves as a Small Entities Compliance Guide (SECG) to aid industry in complying with the requirements of the VFD final rule that published in the **Federal Register** on June 3, 2015 (80 FR 31708). FDA prepared this SECG in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121). In the **Federal Register** of March 28, 2019 (84 FR 11804), FDA announced the availability of a draft revised GFI #120 to provide additional information in response to questions that have been submitted by interested parties since 2015. FDA reviewed comments submitted in response to that notice by stakeholders, including animal producer organizations, the animal feed industry, veterinarians, and producers of electronic VFD software.

The Agency is now announcing the availability of revised GFI #120 which refines and clarifies language in the draft guidance based on stakeholder feedback. Specifically, stakeholders asked FDA to clarify and change language related to the amount of VFD drug in feed, the issuance and effective dates of VFDs, definitions of and requirements for individuals who