721(c) of the Federal Food, Drug, and Cosmetic Act.

**Lowell M. Zeta,**

*Acting Deputy Commissioner for Policy, Legislation, and International Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 516, 520, 522, 529, 556, and 558

**[Docket No. FDA–2025–N–0002]**

## New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Application; Change of Sponsor; Change of Sponsor Address

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

**ACTION:** Final rule; technical amendments.

**SUMMARY:** The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), and conditionally approved new animal drug applications (CNADAs) during July, August, and September 2025. The animal drug regulations are also being amended to improve their accuracy and readability.

**DATES:** This rule is effective February 6, 2026.

**FOR FURTHER INFORMATION CONTACT:** Cathie Marshall, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, *cathie.marshall@fda.hhs.gov,* 240–402–5693.

**SUPPLEMENTARY INFORMATION:**

### I. Approval of Applications

FDA is amending the animal drug regulations to reflect approval actions for NADAs, ANADAs, and CNADAs during July, August, and September 2025, as listed in table 1. Documentation of environmental review required under the National Environmental Policy Act, summaries of the basis of approval under the Freedom of Information Act (FOIA summaries), and marketing exclusivity and patent information are available at Animal Drugs @FDA: *https://animaldrugsatfda.fda.gov/adafda/views/#/search.*

TABLE 1—ORIGINAL, CONDITIONAL, AND SUPPLEMENTAL APPLICATIONS APPROVED DURING JULY, AUGUST, AND SEPTEMBER 2025

| Date of approval | Application No. | Sponsor (drug labeler code [1]) | Product name | Effect of the action | 21 CFR sections |
|---|---|---|---|---|---|
| July 8, 2025 | 200–807 | Huvepharma EOOD (016592) | MGA (melengestrol acetate Type A medicated article) and EXPERIOR (lubabegron Type A medicated article) and MONOVET (monensin Type A medicated article). | Original approval as a generic copy of NADA 141–590. | 558.330 |
| July 8, 2025 | 200–808 | Huvepharma EOOD (016592) | MGA (melengestrol acetate Type A medicated article) and EXPERIOR (lubabegron Type A medicated article) and MONOVET (monensin Type A medicated article) and TYLOVET (tylosin phosphate Type A medicated article). | Original approval as a generic copy of NADA 141–591. | 558.625 |
| July 8, 2025 | 200–815 | Felix Pharmaceuticals Pvt. Ltd. (086101). | Cefpodoxime Proxetil Tablets (cefpodoxime proxetil tablets). | Original approval as a generic copy of NADA 141–232. | 520.370 |
| July 10, 2025 | 141–599 | Intervet, Inc. (000061) | BRAVECTO QUANTUM (fluralaner for extended-release injectable suspension). | Original approval | 522.998 |
| July 11, 2025 | 200–816 | Cronus Pharma Specialities India Private Ltd. (069043). | Meloxisol (meloxicam oral suspension 1.5 mg/mL). | Original approval as a generic copy of NADA 141–213. | 520.1367 |
| July 17, 2025 | 141–607 | Intervet, Inc. (000061) | EXZOLT (fluralaner oral solution) | Original approval | 520.999<br>556.290 |
| July 18, 2025 | 200–759 | ZyVet Animal Health, Inc. (086117). | Furosemide Tablets (furosemide tablets) | Original approval as a generic copy of NADA 034–621. | 520.1010 |
| July 21, 2025 | 200–817 | Felix Pharmaceuticals Pvt. Ltd. (086101). | Meloxicam Oral Suspension (meloxicam oral suspension 1.5mg/mL). | Original approval as a generic copy of NADA 141–213. | 520.1367 |
| August 5, 2025 | 200–818 | Bimeda Animal Health Ltd. (061133). | MOXICLOPRID for dogs (imidacloprid and moxidectin). | Original approval as a generic copy of NADA (141–251). | 524–1146 |
| August 14, 2025 | 200–794 | Cronus Pharma Specialities India Private Ltd. (069043). | MELOXISOL (meloxicam oral suspension 0.5mg/mL). | Original approval as a generic copy of NADA 141–213. | 520.1367 |
| August 28, 2025 | 200–821 | Parnell Technologies Pty. Ltd. (068504). | Isoflurane (isoflurane liquid) | Original approval as a generic copy of NADA 135–773. | 529.1186 |
| August 28, 2025 | 200–819 | Bimeda Animal Health Ltd. (061133). | GAMROZYNE (gamithromycin) | Original approval as a generic copy of NADA 141–328. | 522.1014 |
| September 19, 2025 | 200–824 | Felix Pharmaceuticals Pvt. Ltd. (086101). | Dexmedetomidine (dexmedetomidine hydrochloride sterile injectable solution). | Original approval as a generic copy of NADA 141–267. | 522.558 |
| September 30, 2025 | 141–616 | Zoetis Inc., (054771) | DECTOMAX–CA1 (doramectin injectable solution). | Conditional approval | 516.570 |

[1] See 21 CFR 510.600(c) for sponsor addresses.

### II. Withdrawal of Approval of Applications

Elanco US Inc., 450 Elanco Circle, Indianapolis, IN 46211 (drug labeler code 058198) requested that FDA withdraw approval of the NADA listed in table 2 because the product information has been combined with NADA 010–918. No change to the regulatory text is required.

TABLE 2—APPLICATIONS FOR WHICH APPROVAL WAS VOLUNTARILY WITHDRAWN DURING JULY, AUGUST, AND SEPTEMBER 2025

| Date of withdrawal of approval | Application No. | Product name | 21 CFR section |
|---|---|---|---|
| August 02, 2023[1] ... | 011–948 | HYGROMIX 2.5 (hygromycin B Type A medicated article) ..... | 558.274 |

[1] This withdrawal was not previously published.

## III. Changes of Sponsor

The sponsor of the approved applications listed in table 3 has informed FDA that they have transferred ownership of, and all rights and interest in, these applications to another sponsor. The regulations cited in table 3 are amended to reflect these actions.

TABLE 3—APPLICATIONS FOR WHICH OWNERSHIP WAS TRANSFERRED TO ANOTHER SPONSOR DURING JULY, AUGUST, AND SEPTEMBER 2025

| Application No. | Product name | Transferring sponsor (drug labeler code) | New sponsor (drug labeler code) | 21 CFR section |
|---|---|---|---|---|
| 141–136 ..... | BIO–COX (salinomycin sodium Type A medicated article) and BMD (bacitracin methylenedisalicylate Type A medicated article). | Zoetis Inc. (054771) ..... | Phibro Animal Health Corp. (066104). | 558.550 |
| 091–749 ..... | TYLAN 10 SULFA–G and TYLAN 40 SULFA–G (tylosin phosphate Type A medicated article and sulfamethazine Type A medicated article). | Do ..... | Do ..... | 558.630 |

## IV. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(i)). Although deemed a rule under the FD&C Act, this document does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a ''rule of particular applicability'' and is not subject to the congressional review requirements in 5 U.S.C. 801–808. Likewise, this is not a rule subject to Executive Order 12866.

### List of Subjects

*21 CFR Part 516*

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

*21 CFR Parts 520, 522, and 529*

Animal drugs.

*21 CFR Part 556*

Animal drugs, Dairy products, Foods, Meat and meat products.

*21 CFR Part 558*

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 516, 520, 522, 529, 556, and 558 are amended as follows:

## PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 1. The authority citation for part 516 continues to read as follows:

**Authority:** 21 U.S.C. 360ccc–1, 360ccc–2, 371.

■ 2. Add § 516.570 to read as follows:

### § 516.570 Doramectin.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams of doramectin.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in cattle*—(1) *Amount.* 200 micrograms per kilogram (10 milligrams per 110 pounds).

(2) *Indications for use.* For prevention and treatment of infestations caused by larvae of *Cochliomyia hominivorax* (myiasis), and prevention of reinfestation for 21 days in cattle.

(3) *Limitations.* Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Administer as a single subcutaneous or intramuscular injection. Do not slaughter cattle for human consumption within 35 days of treatment. Not for use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

## PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for part 520 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

### § 520.370 [Amended]

■ 4. In § 520.370, in paragraph (b)(1), remove the text ''No. 017033'' and in its place add the text ''Nos. 017033 and 086101''.

■ 5. Revise the heading of § 520.998 to read as follows:

### § 520.998 Fluralaner chewable tablets.

* * * * *

■ 6. Add § 520.999 to read as follows:

### § 520.999 Fluralaner oral solution.

(a) *Specifications.* Each milliliter (mL) of solution contains 10 milligrams (mg) fluralaner.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in laying hens and replacement chickens*—(1) *Amount.* Administer orally to chickens via the drinking water as 2 single doses, spaced 7 days apart, with each dose consumed over a period of 6 to 24 hours. Each dose is 0.5 mg fluralaner/kilogram (kg) (0.227 mg/pound (mg/lb)) body weight, equivalent to 0.05 mL fluralaner oral solution/kg body weight (0.023 mL/lb).

(2) *Indications for use.* For the treatment and control of northern fowl mites (*Ornithonyssus sylviarum*).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Chickens must not be slaughtered for human consumption for 11 days after the last treatment. No egg discard is required when used according to the labeling.

### § 520.1010 [Amended]

■ 7. In § 520.1010, in paragraph (b)(1), remove the text ''No. 000010'' and in its place add the text ''Nos. 000010 and 086117''.

■ 8. In § 520.1367, revise paragraphs (b)(1) and (2) and the last sentence in paragraph (c)(1) to read as follows:

**§ 520.1367 Meloxicam.**

* * * * *

(b) * * *

(1) Nos. 000010 and 069043 for use of the products described in paragraph (a) of this section; and

(2) Nos. 013744, 055529, and 086101 for use of the product described in paragraph (a)(2) of this section.

(c) * * *

(1) * * * For all treatments after day 1, administer 0.045 mg/lb (0.1 mg/kg) body weight once daily.

* * * * *

## PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 9. The authority citation for part 522 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

**§ 522.558 [Amended]**

■ 10. In § 522.558, in paragraph (b)(1), remove the text ''and 086117'' and in its place add the text ''086101, and 086117''.

■ 11. Add § 522.998 to read as follows:

**§ 522.998 Fluralaner.**

(a) *Specifications.* The product is supplied in two vials, one vial containing 2.51 grams of sterile fluralaner and one vial containing the required 15 milliliters (mL) of sterile vehicle for constitution. Each mL of constituted suspension contains 150 milligrams (mg) fluralaner.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer as a single subcutaneous dose every 12 months or every 8 months in the case of potential exposure to *Amblyomma americanum* ticks. The subcutaneous dose volume is 0.1 mL of the constituted suspension/kilogram (kg) body weight (0.045 mL per pound (mL/lb)). This volume provides a dose of 15 mg fluralaner per kilogram body weight (6.8 mg/lb).

(2) *Indications for use.* Kills adult fleas and for the treatment and prevention of flea infestations (*Ctenocephalides felis*); for the treatment and control of tick infestations *Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), and *Rhipicephalus sanguineus* (brown dog tick) for 12 months in dogs and puppies 6 months of age and older; and for the treatment and control of *Amblyomma americanum* (lone star tick) infestations for 8 months in dogs and puppies 6 months of age and older.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**§ 522.1014 [Amended]**

■ 12. In § 522.1014, in paragraph (b), remove the text ''No. 000010'' and in its place add the text ''Nos. 000010 and 061133''.

■ 13. In § 522.2680 revise paragraphs (d)(1)(ii)(A) and (B) as follows:

**§ 522.2680 Zeranol.**

* * * * *

(d) * * *

(1) * * *

(ii) * * *

(A) For increased rate of weight gain and improved feed efficiency in growing beef steers and heifers fed in confinement for slaughter.

(B) For increased rate of weight gain in beef calves 2 months of age or older, in growing beef steers and heifers on pasture (stocker, feeder, and slaughter), and in growing beef steers and heifers in a dry lot.

* * * * *

## PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 14. The authority citation for part 529 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

**§ 529.1186 [Amended]**

■ 15. In § 529.1186, in paragraph (b), remove the text ''See Nos. 017033, 054771, and 065085'' and in its place add the text ''See Nos. 017033, 054771, 065085, and 068504''.

## PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 16. The authority citation for part 556 continues to read as follows:

**Authority:** 21 U.S.C. 342, 360b, 371.

■ 17. Add § 556.290 to read as follows:

**§ 556.290 Fluralaner.**

(a) *Acceptable daily intake (ADI).* The ADI for total residue of fluralaner is 10 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for parent fluralaner (marker residue) are:

(1) *Chickens.* (i) Liver (target tissue): 320 ppb.

(ii) Muscle: 110 ppb.

(iii) Eggs: 2500 ppb.

(2) [Reserved]

(c) *Related conditions of use.* See § 520.999 of this chapter.

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 18. The authority citation for part 558 continues to read as follows:

**Authority:** 21 U.S.C. 354, 360b, 360ccc, 360ccc–1, 371.

■ 19. In § 558.330, revise paragraph (e)(1)(v) to read as follows:

**§ 558.330 Lubabegron.**

* * * * *

(e) * * *

(1) * * *

| Lubabegron (as lubabegron fumarate) in grams/ton | Combination in grams/ton | Indications for use | Limitations | Sponsors |
|---|---|---|---|---|
| * | * | * | * | * |
| (v) 1.25 to 4.54 | Monensin, 10 to 40 and melengestrol acetate, 0.25 to 2. | Growing beef heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), for reduction of ammonia gas emissions per pound of live weight and hot carcass weight, and for the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii* during the last 14 to 91 days on feed. | Melengestrol acetate Type C top-dress medicated feed (0.5 to 2 lb(s) per head per day) must be top dressed onto or mixed at feeding with a Type C medicated feed containing 1.25 to 4.54 g/ton lubabegron and 10 to 40 g/ton monensin, to provide 0.25 to 0.5 mg melengestrol acetate and 13 to 90 mg lubabegron per head per day, and 0.14 to 0.42 mg monensin per pound of body weight per day, depending upon severity of challenge, up to a maximum of 480 mg monensin per head per day. Feed as the sole ration during the last 14 to 91 days on feed. See special labeling considerations in paragraph (d) of this section, and in §§ 558.342(d) and 558.355(d). Lubabegron fumarate as provided by No. 058198; monensin as provided by No. 058198 or 016592; melengestrol acetate as provided by No. 054771 in § 510.600(c) of this chapter. | 058198<br>016592 |

* * * * *

■ 20. In § 558.550, revise paragraphs (e)(1)(ii) through (iv) to read as follows:

**§ 558.550 Salinomycin.**

* * * * *

(e) * * *

(1) * * *

| Salinomycin sodium activity in grams/ton | Combination in grams/ton | Indications for use | Limitations | Sponsor |
|---|---|---|---|---|
| * | * | * | * | * |
| (ii) 40 to 60 | Bacitracin (as feed grade bacitracin methylenedisalicylate) 4 to 50. | Broiler chickens and replacement chickens. Not for use in laying hens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and for increased rate of weight gain and improved feed efficiency. | Feed continuously as sole ration. Discontinue use prior to sexual maturity. The dosage of salinomycin sodium should be adjusted to meet the severity of the coccidial challenge, which varies with environmental and management conditions. May be fatal if fed to adult turkeys or horses. Salinomycin as provided by No. 016592; bacitracin methylenedisalicylate as provided by No. 066104 in § 510.600(c) of this chapter. | 016592<br>066104 |
| (iii) 40 to 60 | Bacitracin (as feed grade bacitracin methylenedisalicylate) 50. | Broiler chickens and replacement chickens. Not for use in laying hens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin methylenedisalicylate. | Feed continuously as sole ration. Discontinue use prior to sexual maturity. The dosage of salinomycin sodium should be adjusted to meet the severity of the coccidial challenge, which varies with environmental and management conditions. May be fatal if fed to adult turkeys or horses. Salinomycin as provided by No. 016592; bacitracin methylenedisalicylate as provided by No. 066104 in § 510.600(c) of this chapter. | 066104 |
| (iv) 40 to 60 | Bacitracin (as feed grade bacitracin methylenedisalicylate) 100 to 200. | Broiler chickens and replacement chickens. Not for use in laying hens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin methylenedisalicylate. | Feed continuously as the sole ration. Discontinue use prior to sexual maturity. The dosage of salinomycin sodium should be adjusted to meet the severity of the coccidial challenge, which varies with environmental and management conditions. To control a necrotic enteritis outbreak, start medication at the first clinical signs of disease. The bacitracin methylenedisalicylate dosage range permitted provides for different levels based on severity of the infection. Consult a poultry diagnostic laboratory or pathologist to determine the diagnosis and advice regarding the optimal level of bacitracin methylenedisalicylate. Administer continuously for 5–7 days or as long as clinical signs persist, and then reduce bacitracin methylenedisalicylate dosage to prevention level (50 g/ton). May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by No. 016592; bacitracin methylenedisalicylate as provided by No. 066104 in § 510.600(c) in this chapter. | 066104 |
| * | * | * | * | * |

* * * * *

■ 21. In § 558.625, revise paragraph (e)(2)(ix) to read as follows:

**§ 558.625 Tylosin.**

* * * * *

(e) * * *

(2) * * *

| Tylosin in grams/ton | Combination in grams/ton | Indications for use | Limitations | Sponsors |
|---|---|---|---|---|
| * | * | * | * | * |
| (ix) 8 to 10 | Monensin, 10 to 40 plus lubabegron (as lubabegron fumarate), 1.25 to 4.54, plus melengestrol acetate, 0.25 to 2.0. | Growing beef heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), for reduction of ammonia gas emissions per pound of live weight and hot carcass weight, for the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii,* and for reduction of incidence of liver abscesses associated with *Fusobacterium necrophorum* and *Arcanobacterium pyogenes* during the last 14 to 91 days on feed. | Feed as the sole ration during the last 14 to 91 days on feed. Melengestrol acetate Type C top-dress medicated feed (0.5 to 2.0 lb per head per day) must be top dressed onto or mixed at feeding with a Type C medicated feed containing 8 to 10 g/ton tylosin, 1.25 to 4.54 g/ton lubabegron, and 10 to 40 g/ton monensin, to provide 0.25 to 0.5 mg melengestrol acetate, 60 to 90 mg tylosin per head per day, 13 to 90 mg lubabegron per head per day, and 0.14 to 0.42 mg monensin per pound of body weight per day, depending on severity of challenge, up to 480 mg monensin per head per day. See special labeling considerations in §§ 558.330(d), 558.342(d), and 558.355(d). Tylosin and monensin as provided by No. 058198 or 016592; lubabegron fumarate as provided by No. 058198; melengestrol acetate as provided in No. 054771 in § 510.600(c) of this chapter. | 058198<br>016592 |
| * | * | * | * | * |

**§ 558.630 [Amended]**

■ 22. In § 558.630:

■ a. In paragraph (b)(2), remove the text ''054771'' and in its place add the text ''066104''; and

■ b. In the table in paragraph (e)(2), in the ''Sponsor'' column, remove the text ''054771'' and in its place add the text ''066104''.

**Lowell M. Zeta,**

*Acting Deputy Commissioner for Policy, Legislation, and International Affairs.*

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**BILLING CODE 4164–01–P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

### 32 CFR Part 220

**[Docket ID: DoD–2022–HA–0054]**

**RIN 0720–AB87**

## Medical Billing for Healthcare Services Provided by Department of Defense Military Medical Treatment Facilities to Civilian Non-Beneficiaries

**AGENCY:** Defense Health Agency (DHA), Department of Defense (DoD).

**ACTION:** Final rule.

**SUMMARY:** As required by the James M. Inhofe National Defense Authorization Act for Fiscal Year 2023 (NDAA–23), this rule reduces financial harm to civilians who are not covered beneficiaries of the Military Health System (MHS), and who receive healthcare services at DoD military medical treatment facilities (MTF). The rulemaking implements the MHS Modified Payment and Waiver Program (MPWP) through which the DoD applies a sliding fee scale and/or a catastrophic fee waiver to medical invoices of certain non-beneficiaries and accepts payments from health insurers of non-beneficiaries as full payment except for copays, coinsurance, deductibles, nominal fees and non-covered services.

**DATES:** This rulemaking is effective on March 9, 2026.

**FOR FURTHER INFORMATION CONTACT:** Ms. Merlyn Jenkins, phone number: (703) 681–8812, mailing address: Office of the Secretary of Defense for Health Affairs, Health Resources Management and Policy, 1200 Defense Pentagon, Washington, DC 20301–1200; email address: *merlyn.jenkins.civ@health.mil.*

**SUPPLEMENTARY INFORMATION:** The NDAA–23 also grants the Director of DHA discretionary authority to waive assessment of medical fees of non-beneficiaries when the healthcare provided enhances the knowledge, skills, and abilities (KSAs) of healthcare providers, as determined by the Director of DHA. The DHA is implementing the amendments to 10 U.S.C. 1079b enacted through the NDAA–23. By statute (Pub. L. 117–263, div. A, title VII, § 716(c), Dec. 23, 2022, 136 Stat. 2661), the sliding fee scale and/or catastrophic fee waivers apply to bills for healthcare services provided at MTFs on or after June 21, 2023.

### I. Background and Authority

Title 10, United States Code (U.S.C.), section 1073d requires the DoD to maintain MTFs for the purposes of supporting the medical readiness of the armed forces and the readiness of deployable medical personnel. To maintain medical currency and bolster the KSAs of DoD healthcare providers, the DoD renders emergency, trauma, and other medical services to beneficiaries of the MHS which consist of service members and former service members, and their dependents. The MHS may provide healthcare services to other individuals who are not eligible beneficiaries, in certain circumstances, as authorized by law, and typically on a reimbursable basis (Pub. L. 114–328, 717(c), Dec. 23, 2016, as amended (10 U.S.C. 1071 note); and § 1074(c)).

Regulations implementing DoD's authority under 10 U.S.C. 1095 and related provisions of law to compute reasonable charges for inpatient and ambulatory (outpatient) care provided by MTFs, including charges for pharmaceuticals, durable medical equipment, supplies, immunizations, injections, or other medications, are at 32 CFR part 220, last updated on August 20, 2020 (55 FR 21742–21750). Medical billing is structured under three existing healthcare cost recovery programs: Third Party Collections (10 U.S.C. 1095); Medical Services Account (10 U.S.C. 1079b, 1085, and 1104); and Medical Affirmative Claims (42 U.S.C. 2651–2653). The rates used for billing are modeled after the rates published by the Centers for Medicare & Medicaid Services. The rates are approved annually by the Assistant Secretary of Defense for Health Affairs (ASD(HA)) and published on the DoD Comptroller's website at *https://comptroller.defense.gov/Financial-Management/Reports/rates2023/.* Funds collected