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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### 2 CFR Part 376

42 CFR Parts 23, 51c, 52i, 56, 57, 63, and 124

45 CFR Parts 3, 63, and 75

48 CFR Parts 302 and 326

[Docket Number HHS–OS–2020–0015]

RIN 0991–AC19

### Food and Drug Administration

21 CFR Parts 1, 5, 12, 14, 25, 81, 133, 172, 178, 184, 201, 310, 369, 501, and 582

### Centers for Medicare & Medicaid Services

42 CFR Parts 411, 412, 422, 423, 426, 440, 441, 447, 482, and 485

### Office of Inspector General

42 CFR Parts 1004 and 1008

### Administration for Children and Families

45 CFR Parts 305, 307, 1324, 1325, 1326, and 1328

### Regulatory Clean Up Initiative

**AGENCY:** Office of the Assistant Secretary for Administration (ASA), HHS.

**ACTION:** Final rule.

**SUMMARY:** The U.S Department of Health and Human Services (HHS) is amending its regulations to make miscellaneous corrections, including correcting references to other regulations, misspellings and other typographical errors. This document is necessary to inform the public of these non-

substantive changes to HHS's regulations.

**DATES:** This rule is effective as of December 16, 2020.

**FOR FURTHER INFORMATION CONTACT:** Douglas Cheung, Ph.D., ReImagine Transformation Management Office, Immediate Office of the Secretary, email: [douglas.cheung@hhs.gov](mailto:douglas.cheung@hhs.gov); and [RegCleanUp@hhs.gov](mailto:RegCleanUp@hhs.gov).

#### SUPPLEMENTARY INFORMATION:

#### I. Introduction

HHS is committed to advancing its mission in part through strong regulatory stewardship, including regularly reviewing and modernizing its regulations, in accordance with the principles, *inter alia*, established in Executive Order 13563 (Jan. 18, 2011). Section 6 of E.O. 13563 (76 FR 3821) guides the process of the retrospective review of existing regulations by agencies. While retrospective regulatory review and reform has until now been a largely manual process, new technologies exist that can support policy subject matter experts (SMEs) in their efforts to review large amounts of regulatory text. As part of HHS's pioneering efforts to pilot the use of Artificial Intelligence (AI) and other advanced analyses, HHS recently applied AI and Natural Language Processing (NLP) technology to support and accelerate SME reviews in cognizant divisions of HHS of unstructured text in the Code of Federal Regulations (CFR), facilitating the identification of opportunities to improve HHS's regulations.

In conjunction with, and following validation by, human SMEs, this AI-augmented analysis indicated that HHS has a number of "incorrect citations," in which a current regulation cites a regulation that may have moved or may no longer exist. In response to these findings, HHS is amending the identified "incorrect citations." The amendments detailed in this rule correct these citations, remove erroneous language, or correct misspellings and other typographical errors.

#### II. Background

HHS is committed to the Administration's vision of reducing regulatory burden and modernizing the CFR. Executive Order 13771 (Jan. 30, 2017) (82 FR 9339) and E.O. 13563 both emphasize the importance of

retrospectively reviewing existing regulations in order to achieve these objectives. In particular, section 6 of E.O. 13563 asks agencies to "consider how best to promote retrospective analyses of rules that may be outmoded . . ." (76 FR 3822). HHS has continued to execute regulatory reform through new and innovative methods. In the past, regulatory analysis and reform has been a largely manual process, limited by each expert's experience with a particular subset of agency regulations, and it has been labor-intensive and time-consuming to find regulatory reform opportunities through this manual review. In addition, unless a portfolio of minor changes can occur through a consolidated regulatory vehicle, it is often administratively impractical to implement many results of retrospective review; this relative infeasibility of implementation may in turn discourage the identification and correction of many small but valuable refinements to existing regulations.

However, HHS has piloted a new method of regulatory analysis, using an AI-driven tool that analyzed HHS's regulations using NLP as applied to the regulatory text in the CFR. This NLP analysis is designed to accelerate and augment expert review, by highlighting "candidate" provisions that could be outmoded, allowing HHS SMEs to focus on these provisions as potential areas of opportunity for modernization. The NLP analysis revealed numerous reform opportunities, including instances where a regulation citation is now incorrect. Combined with the policy expertise of HHS SMEs, this NLP analysis method has yielded promising results towards reforming and modernizing regulations at HHS. The revisions outlined in this rule represent a portion of the results from this effort, and are focused on administrative, non-substantive changes that will clean up HHS's regulations. For efficiency, a consolidated regulatory vehicle is being used to implement these numerous non-substantive changes across multiple HHS regulations. Future uses of these technologies to promote comprehensive and systematic retrospective review will continue to algorithmically refine identification of potentially "outmoded" regulations and will seek algorithmic characterization of other regulatory targets of E.O. 13563—regulations which are "ineffective,

insufficient, or excessively burdensome”, as candidates for SME review and potential reform.

### III. Summary of Changes

#### 2 CFR Part 376

- *Deletion.* In 2 CFR 376.10, this rule removes the incorrect references to 3 CFR 1986 Comp., p. 189 and 3 CFR 1989 Comp., p. 235 as these references no longer exist. Although 3 CFR 1986 and 3 CFR 1989 are referenced as sources for Executive Order 12549 “Debarment and Suspension” (signed February 18, 1986) and Executive Order 12689 “Debarment and Suspension (signed August 18, 1989), removal of these references ensure consistency with 2 CFR 276.10 as currently written.

#### 21 CFR Part 1

- *Correct Reference.* In 21 CFR 1.24(a)(6)(ii) and (8)(ii), this rule removes the incorrect reference 21 CFR 101.105 and replaces it with the correct reference 21 CFR 101.7 as 21 CFR 101.105 was redesignated in 2016 as part of a technical amendment (81 FR 59130).

#### 21 CFR Part 5

- *Correct an Omission.* In 21 CFR 5.1100, a footnote “\*” next to the “Office of Chief Counsel,” that had appeared in earlier editions and was inadvertently omitted, should be inserted to read as it had in prior editions, as follows: “\*The Office of the Chief Counsel (also known as the Food and Drug Division, Office of the General Counsel, Department of Health and Human Services), while administratively within the Office of the Commissioner, is part of the Office of the General Counsel of the Department of Health and Human Services.”

- *Correct an Omission.* In 21 CFR 5.1105, a footnote “\*” next to the “Office of Chief Counsel,” that had appeared in earlier editions and was inadvertently omitted, should be inserted to read as it had in prior editions, as follows: “\*The Office of the Chief Counsel (also known as the Food and Drug Division, Office of the General Counsel, Department of Health and Human Services), while administratively within the Office of the Commissioner, is part of the Office of the General Counsel of the Department of Health and Human Services.”

#### 21 CFR Part 12

- *Deletion.* In 21 CFR 12.21(a)(2), this rule deletes the phrase “514.2 for applications for animal feeds” as 21 CFR 514.2 was removed in 1999 (64 FR 63195) to provide for feed mill licensing

in accordance with the Animal Drug Availability Act (ADAA) of 1996.

#### 21 CFR Part 14

- *Correct Reference.* In 21 CFR 14.7(b), this rule removes the incorrect reference 45 CFR 5.34 and replaces it with the correct reference 45 CFR 5.61—45 CFR 5.64 (subpart F Appeals) as 45 CFR 5.34 was removed when the Freedom of Information regulations were reorganized in 2016 (81 FR 74930).

#### 21 CFR Part 25

- *Deletion.* This rule deletes and reserves 21 CFR 25.33(a)(7), which reads “(7) Approval of a drug for use in animal feeds if such drug has been approved under § 514.2 or 514.9 of this chapter for other uses,” as 21 CFR 514.2 and 21 CFR 514.9 were removed in 1999 (64 FR 63195) to provide for feed mill licensing in accordance with the Animal Drug Availability Act (ADAA) of 1996.

#### 21 CFR Part 81

- *Deletion.* In 21 CFR 81.30(s)(2), this rule deletes the sentence “Ingested drug lip products, however, are regulated for use in 74.1308 and 74.1309” in order to remove the incorrect references to 21 CFR 74.1308 and 21 CFR 74.1309. This language is no longer needed because 21 CFR 74.1308 and 21 CFR 74.1309 were removed in 1988 (53 FR 26766).

- *Deletion.* This rule deletes 21 CFR 81.32. This language is no longer needed because it cross-references a section, 21 CFR 81.25, that was removed in 1988 (53 FR 33110).

#### 21 CFR Part 133

- *Deletion.* This rule deletes 21 CFR 133.116(d), which reads “(d) Low sodium cheddar cheese is subject to § 105.69 of this chapter” as 21 CFR 105.69 was revoked in 1996 (61 FR 27771).

- *Deletion.* This rule deletes 21 CFR 133.121(f) which reads “(f) Low sodium colby cheese is subject to § 105.69 of this chapter” as 21 CFR 105.69 was revoked in 1996 (61 FR 27771).

#### 21 CFR Part 172

- *Deletion.* In 21 CFR 172.840(c)(13), this rule deletes “and 133.131” as this section was revoked in 1996 (61 FR 58991) after FDA determined that lowfat cottage cheese was more appropriately covered by the general standard in 21 CFR 130.10.

#### 21 CFR Part 178

- *Correct Reference.* In 21 CFR 178.3730, this rule removes the incorrect references to 21 CFR 193.390, 21 CFR 561.310, and 21 CFR 561.340 and replaces them with the correct

references 40 CFR 180.127 and 40 CFR 180.128. This change reflects a renumbering of the CFR in 1988 (53 FR 24666) and a consolidation of certain tolerance regulations in 2000 (65 FR 33703).

- *Deletion.* In 21 CFR 178.3730, this rule removes the incorrect reference to 21 CFR 193.60 as this rule was renumbered in 1988 (53 FR 24666) and revoked in 1989 (54 FR 43424).

#### 21 CFR Part 184

- *Correct Reference.* In 21 CFR 184.1097, this rule removes the incorrect reference to 9 CFR 318.7 and replaces it with the correct reference 9 CFR 424.21. This change reflects a renumbering of the CFR in 1999 (64 FR 72168).

- *Correct Reference.* In 21 CFR 184.1143, this rule removes the incorrect reference to 21 CFR 170.1 and replaces it with the correct reference 21 CFR 170.3(n)(22) as the definition for “gelatins and puddings” was moved in 1977 (42 FR 14302).

- *Correct Reference.* In 21 CFR 184.1924(c)(1), this rule removes the incorrect reference to 27 CFR 2.5 and replaces it with the correct reference 27 CFR 1.10 as the definition reference was moved in 1996 (61 FR 26096) and moved again in 1999 (64 FR 49985).

#### 21 CFR Part 201

- *Deletion.* This rule removes a clause in 21 CFR 201.317(c) that cross-references 21 CFR 310.500, which was revoked in 2002 (67 FR 42992, 42997).

#### 21 CFR Part 310

- *Deletion.* This rule removes 21 CFR 310.303 as it concerns procedures to list a drug in 21 CFR 310.304, which was revoked as obsolete or no longer necessary to achieve public health goals in 1996 (61 FR 29476, 29477).

#### 21 CFR Part 369

- *Correct Reference.* In 21 CFR 369.3, this rule removes the incorrect reference to 21 CFR 369.22, which was removed in 2002 (67 FR 4904, 4907).

#### 21 CFR Part 501

- *Deletion.* In 21 CFR 501.105(t), this rule removes the incorrect reference to 21 CFR 564.14(b) as 21 CFR part 564 was removed in 1999 (64 FR 4293) as an unnecessary regulation.

#### 21 CFR Part 582

- *Correct Reference.* In 21 CFR 582.99, this rule removes the incorrect references to 40 CFR 180.1001(c) and (d) and replaces them with the correct references of 40 CFR 180.910 and 40 CFR 180.920 as these references were renumbered in 2004 (69 FR 23113).

*42 CFR Part 23*

- *Correct Reference.* This rule amends § 23.9 to remove the phrase “the most recent ‘CSA Income Poverty Guidelines’ (45 CFR 1060.2) issued by the Community Services Administration;” and replace it with “the poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2);”. The Secretary of HHS is required to update the poverty guidelines at least annually, adjusting them based on the Consumer Price Index for All Urban Consumers. 45 CFR 1060.2 no longer exists; rather, updates are published at least annually in the **Federal Register**.

*42 CFR Part 51c*

- *Correct Reference.* Section 51c.107(5) is amended to remove the phrase “the most recent ‘CSA Income Poverty Guidelines’ (45 CFR 1060.2) issued by the Community Services Administration;” and replace it with “the poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2);”. The Secretary of HHS is required to update the poverty guidelines at least annually, adjusting them based on the Consumer Price Index for All Urban Consumers. 45 CFR 1060.2 no longer exists; rather, updates are published at least annually in the **Federal Register**.

- *Correct Reference.* Section 51c.303 is amended to remove the phrase “the most recent ‘CSA Income Poverty Guidelines’ (45 CFR 1060.2) issued by the Community Services Administration;” and replace it with “the poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2);”. The Secretary of HHS is required to update the poverty guidelines at least annually, adjusting them based on the Consumer Price Index for All Urban Consumers. 45 CFR 1060.2 no longer exists; rather, updates are published at least annually in the **Federal Register**.

*42 CFR Part 52i*

- *Correct Reference.* In § 52i.11b, this rule removes the incorrect reference to 45 CFR 74.53 and replaces it with the correct reference 45 CFR 75.361. This change reflects an update to the referenced citation.

- *Correct Reference.* In § 52i.11c, this rule removes the incorrect reference to 45 CFR 74.53e and replaces it with the correct reference 45 CFR 75.364. This

change reflects an update to the referenced citation.

- *Correct Reference.* In § 52i.11d, this rule removes the incorrect reference to 45 CFR 74.52 and replaces it with the correct reference 45 CFR 75.341. This change reflects an update to the referenced citation.

*42 CFR Part 56*

- *Correct Reference.* Section 56.108 is amended to remove the phrase “the most recent ‘CSA Income Poverty Guidelines’ (45 CFR 1060.2) issued by the Community Services Administration;” and replace it with “the poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2);”. The Secretary of HHS is required to update the poverty guidelines at least annually, adjusting them based on the Consumer Price Index for All Urban Consumers. 45 CFR 1060.2 no longer exists; rather, updates are published at least annually in the **Federal Register**.

- *Correct Reference.* Section 56.303 is amended to remove the phrase “the most recent ‘CSA Income Poverty Guidelines’ (45 CFR 1060.2) issued by the Community Services Administration;” and replace it with “the poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2);”. The Secretary of HHS is required to update the poverty guidelines at least annually, adjusting them based on the Consumer Price Index for All Urban Consumers. 45 CFR 1060.2 no longer exists; rather, updates are published at least annually in the **Federal Register**.

*42 CFR Part 57*

- *Deletion.* Section 57.1505 is amended to remove the incorrect reference to 57.110 as it no longer exists.

*42 CFR Part 63*

- *Correct Reference.* In § 63.2, this rule removes the incorrect reference to 50.102 and replaces it with the correct reference 42 CFR part 93.103. This rule also amends the language to remove the outdated phrase “misconduct of science” and replaces it with the correct, current terminology “research misconduct”.

- *Revised Nomenclature.* In § 63.9(b), this rule removes the outdated phrase “misconduct of science” and replaces it with the correct, current terminology “research misconduct”.

*42 CFR Part 124*

- *Correct Reference.* In § 124.511, this rule removes the incorrect reference to 42 CFR 125.510 as this regulation no longer exists.

- *Correct Reference.* In § 124.602, this rule removes the incorrect reference to 42 CFR 53.1 as it is no longer necessary. This citation references Title VI of the Public Health Service Act, which was repealed in 1979 and has not received Congressional funding since the late 1980’s.

*42 CFR Part 411*

- *Correct Reference.* In § 411.353(d), this rule removes the incorrect reference to § 1003.101 and replaces it with the correct reference § 1003.110. This change is necessary as HHS OIG re-designated the section referenced in this citation in a December 7, 2016 regulation (81 FR 88334). The December 7, 2016 regulation made no substantive changes to this provision.

*42 CFR Part 412*

- *Correct Reference.* In § 412.42, this rule removes all incorrect references to § 405.310 and replaces them with the correct references § 411.15. These changes are necessary as § 405.310 was renumbered in the early 1980’s, and the reference needs to be updated accordingly.

*42 CFR Part 422*

- *Correct Reference.* In § 422.304(f), this rule removes the incorrect reference to § 495.220 and replaces it with the correct reference § 495.204. The Medicare and Medicaid Programs; Electronic Health Record Incentive Program final rule (75 FR 44314), published July 28, 2010, states that 42 CFR 422.304 would be amended to add a new paragraph (f), which would “act as a cross-reference to MA EHR incentive payment rules in subpart C of part 495 of this chapter” (75 FR 44481). Section 422.304(f), as added by the July 28, 2010 final rule, erroneously references § 495.220. This citation was incorrect at the time final rule was adopted; the regulations subpart C of part 495 do not include a § 495.220. Section 422.304(f) should instead have cross-referenced § 495.204 (“Incentive payments to qualifying MA organizations for MA-EPs and MA-affiliated eligible hospitals”).

- *Correct Reference.* In § 422.322(b), this rule removes the incorrect reference to 413.86(d) and replaces it with the correct reference § 413.76. Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates; Final Rule (69 FR 48916), published on August 11,

2004 states that § 413.86(d) would be redesignated into nine separate sections (§ § 413.75, 413.76, 413.77, 413.78, 413.79, 413.80, 413.81, 413.82, and 413.83). Section 422.322 of “The Medicare Program; Establishment of the Medicare Advantage Program; Final Rule (70 FR 4729), published Jan 28, 2005, incorrectly cited § 413.86(d) which existed before the Final Rule 69 FR 48916 split the section into nine separate sections. Section 422.322(b) should have cross-referenced § 413.76 (Direct GME payments: Calculation of payments for GME costs) in place of § 413.86(d).

• *Correct Reference.* In § 422.324(b)(2), this rule removes the incorrect reference to § 413.86(b) and replaces it with the correct reference § 413.75(b). In a final rule published on August 11, 2004, § 413.86 was removed because the size of the section had grown too voluminous. The contents of the section were redesignated into nine individual sections (§ § 413.75 through 413.83). At that time however, the agency failed to update this reference to the section in § 422.324(b)(2).

• *Correct Reference.* In § 422.1094(b)(2), this rule removes the incorrect reference to § 422.858 and replaces it with the correct reference § 422.1088. Subpart T (consisting of § § 422.1000 through 422.1094) was added to part 422 on December 5, 2007 (72 FR 68727). The reference to § 423.858 was a typographical error in that document as that section did not exist at that time and was not otherwise mentioned in the document. The change is necessary to make this technical correction.

#### 42 CFR Part 423

• *Correct Reference.* In § 423.1094(b)(2), this rule removes the incorrect reference to § 423.858 and replaces it with the correct reference § 423.1088. Subpart T (consisting of § § 423.1000 through 423.1094), was added on December 5, 2007 (72 FR 68736). At that time, the reference to § 423.858 in § 423.1094 was a typographical error in that document as that section did not exist at that time and was not otherwise mentioned in the document adding subpart T. The change is necessary to make this technical correction.

• *Correct Reference.* In § 423.2330(c)(3), this rule removes the incorrect reference to § 423.2306(b)(4) and replaces it with the correct reference § 423.2315(b)(4). Subpart W (consisting of 423.2300 through 423.2345) was added to part 423 on April 12, 2012 (71 FR 22172). In that document, the reference to § 423.2306

was a typographical error as that section did not exist at that time and was not included in the subpart being added. The change is necessary to make this technical correction.

#### 42 CFR Part 426

• *Correct Reference.* In § 426.110, paragraph 1 of the definition of “Proprietary data and Privileged information”, this rule removes the incorrect reference to 45 CFR 5.65 and replaces it with the correct reference 45 CFR 5.31(d) and (e). This reference has been included in § 426.110 since it was adopted on November 7, 2003 (68 FR 63716), however, on October 28, 2016 (81 FR 74939), the Department published a final rule revising part 5. That revision moved the substantive text which had been in § 5.65 to 45 CFR 5.31(d) and (e). This change is necessary to make this technical correction.

#### 42 CFR Part 440

• *Correct Reference.* In § 440.20(b) introductory text, this rule removes the incorrect reference to § 481.1 and replaces it with the correct reference § 491.2. There is no citation § 481.1 in the CFR. § 491.2 defines Nurse Practitioners and Physician Assistants for Rural Health Clinics and is the appropriate reference for § 440.20(b).

#### 42 CFR Part 441

• *Correct Reference.* In § 441.17(a)(1), (a)(4), and (b), this rule removes the incorrect references to § 405.1316, § 405.1128(a), and § 405.1316(f), respectively, and replaces them with the correct reference “part 493 of this chapter”. These citations have been rescinded and updated under Medicare regulations but the corresponding Medicaid regulations that reference them were not updated.

• *Correct Reference.* In § 441.18(c) introductory text, this rule removes the incorrect reference to § 441.169 and replaces it with the correct reference § 440.169. This reference was correct in the October 1, 2008 edition on the CFR, however on June 30, 2009 at 74 FR 31196, CMS revised paragraph (c) and this amendment contained a typographical error that resulted in this reference being incorrectly changed.

#### 42 CFR Part 447

• *Correct Reference.* In § 447.299(c), this rule removes the incorrect reference to § 455.204 and replaces it with the correct reference “§ 455.304 of this chapter”. The current reference is a typographical error and does not exist. This change is necessary to make this technical correction.

#### 42 CFR Part 482

• *Correct Reference.* In 42 CFR 482.27(b)(3)(iii) and 482.27(b)(4)(iii), this rule removes the incorrect references to 21 CFR 610.48 as, effective December 28, 2015, the FDA issued a final rule that removed and reserved 21 CFR 610.48 in its entirety, along with any reference to this requirement in the FDA’s other requirements. This rule also revises the remaining text of our provisions at 42 CFR 482.27(b)(3)(iii) and 482.27(b)(4)(iii), which contained references to 21 CFR 610.48(b)(3) and 610.48(c)(2), respectively.

#### 42 CFR Part 485

• *Correct Reference.* In § 485.639(c)(1)(vii), this rule removes the incorrect reference to 42 CFR 413.86 as it no longer exists and adds in its place, a reference to § 413.76 through 413.83. In a previous group of technical amendments (FY 2005 IPPS final rule) (69 FR 49234), CMS redesignated the contents of § 413.86 as § § 413.75 through 413.83. They also updated cross-references to § 413.86 that were located in various sections under 42 CFR parts 400 through 499. They inadvertently did not capture all of the needed cross-reference changes.

#### 42 CFR Part 1004

• *Correct Reference.* In § 1004.40, this rule removes the incorrect reference to 476.139 and replaces it with the correct reference 480.139. This non-substantive technical change is necessary to reference the correct regulation section that was moved.

#### 42 CFR Part 1008

• *Correct Reference.* In § 1008.36, this rule removes the incorrect reference to 45 CFR 5.65 and replaces it with the correct reference 45 CFR 5.41. This non-substantive technical change is necessary to reference the correct regulation section that was moved.

#### 45 CFR Part 3

• *Correct Reference.* In § 3.1, this rule removes the incorrect reference to 40 United States Code section 318 or 318d and replaces it with the correct reference U.S. Public Law 107–296, Homeland Security Act of 2002. This amendment reflects a change in the referenced statutory authority.

• *Correct Reference.* In § 3.2(f), this rule removes the incorrect reference to Article 27, Sec. 36 in row 5 the table and replaces it with the correct reference Criminal Law, Sec. 4–202; removes the incorrect reference to Article 27, Sec. 36B in row 6 of the table and replaces it with the correct reference Sec. 4–202; removes the

incorrect reference to Article 27, Sec. 36B in row 7 of the table and replaces it with the correct reference Criminal Law, Sec. 4–204; removed the incorrect reference to Article 27, Sec. 122 in row 8 of the table and replaces it with the correct reference Criminal Law, Sec. 6–409; removes the incorrect reference to Article 27, Secs. 240, 245 in row 9 of the table and replaces it with the correct reference Criminal Law, Sec. 12–102. These changes update the citations in the referenced Maryland codes.

- *Correct Reference.* In § 3.5, this rule removes the incorrect reference to 41 CFR 101–45.304 and replaces it with the correct reference 41 CFR part 102–41; removes the incorrect reference to 41 CFR part 101–48 and replaces it with the correct reference 41 CFR 102; removed the incorrect reference to 41 CFR 101–48.305 and replaces it with the correct reference 41 CFR 102–41. These changes reflect updates to the referenced General Services Administration regulations.

- *Correct Reference.* In § 3.61, this rule removes the incorrect reference to 40 United States Code section 318 or 318d and replaces it with the correct reference U.S. Public Law 107–296, Homeland Security Act of 2002. This amendment reflects a change in the referenced statutory authority.

#### 45 CFR Part 63

- *Correct Reference.* In § 63.1, this rule removes the incorrect reference to 41 CFR 3–1.53 (which was not implemented into a final rule and is obsolete) and replaces it with the correct reference 45 CFR 75.201(a), and removes the incorrect reference to 41 CFR Chapters 1 and 3 (which is obsolete and has been replaced by the Federal Acquisition Regulations System (FAR) at 48 CFR) and replaces it with the correct reference 48 CFR Chapter 3.

#### 45 CFR Part 75

- *Correct Reference.* In § 75.372, this rule removes the incorrect reference to 45 CFR 75.390 and replaces it with the correct reference 45 CFR 75.386, so that the sentence now reads “the requirements of 75.381 and 75.386”. The current citation of “the requirements of 75.381 through 75.390” is no longer accurate as §§ 75.382 through 75.485 and §§ 75.387 through 75.390 are now reserved.

#### 45 CFR Part 305

- *Correct Reference.* Section 305.0 is amended in the beginning of the last sentence by replacing “Sections 305.40 through 305.42 . . .” with “Sections 305.40, 305.42 . . .” which removes the first instance of “through” in the

sentence and replaces with a comma. This change is not substantive and clarifies the sentence.

#### 45 CFR Part 307

- *Correct Reference.* In § 307.5(d)(3), this rule removes the incorrect reference to 45 CFR 305.99 and replaces it with the correct reference 45 CFR 305.66. This change is not substantive and is necessary to make this technical correction.

#### 45 CFR Part 1324

- *Correct Reference.* In § 1324.11, this rule removes the incorrect reference to 45 CFR 1327.13(e) and replaces it with the correct reference 45 CFR 1324.13(e); removes two incorrect references to 45 CFR 1327.19(b)(5) and replaces them with the correct reference 1324.19(b)(5) through (8); removes the incorrect reference to 45 CFR 1327.21 and replaces it with the correct reference 45 CFR 1324.21. 45 CFR 1327 was moved to 45 CFR 1324 in 2016 by 81 FR 35644 reflecting the Administration for Community Living’s 2012 reorganization in a single subchapter of the regulations. The text of statutes was not completely updated to align with this final rule.

- *Correct Reference.* In § 1324.15, this rule removes the incorrect reference to 45 CFR 1327.13(e) and replaces it with the correct reference 1324.13(e); removes the incorrect reference to 45 CFR 1327.13(g) and replaces it with the correct reference 45 CFR 1324.13(g); removes the incorrect reference to 45 CFR 1327.13(c)(2) and replaces it with the correct reference 1324.13(c)(2). 45 CFR 1327 was moved to 45 CFR 1324 in 2016 by 81 FR 35644 reflecting the Administration for Community Living’s 2012 reorganization in a single subchapter of the regulations. The text of statutes was not completely updated to align with this final rule.

- *Correct Reference.* In § 1324.19(b)(6), this rule removes the incorrect reference to 45 CFR 1327.11(e)(3) and replaces it with the correct reference 45 CFR 1324.11(e)(3). 45 CFR 1327 was moved to 45 CFR 1324 in 2016 by 81 FR 35644 reflecting the Administration for Community Living’s 2012 reorganization in a single subchapter of the regulations. The text of statutes was not completely updated to align with this final rule.

- *Correct Reference.* In § 1324.19(b)(7), this rule removes the incorrect reference to 45 CFR 1327.11(e)(3) and replaces it with the correct reference 45 CFR 1324.11(e)(3). 45 CFR 1327 was moved to 45 CFR 1324 in 2016 by 81 FR 35644 reflecting the Administration for Community Living’s

2012 reorganization in a single subchapter of the regulations. The text of statutes was not completely updated to align with this final rule.

- *Correct Reference.* In § 1324.19(b)(8), this rule removes the incorrect reference to 45 CFR 1327.11(e)(3) and replaces it with the correct reference 45 CFR 1324.11(e)(3). 45 CFR 1327 was moved to 45 CFR 1324 in 2016 by 81 FR 35644 reflecting the Administration for Community Living’s 2012 reorganization in a single subchapter of the regulations. The text of statutes was not completely updated to align with this final rule.

- *Deletion.* In § 1324.21(b)(3), this rule amends the language “(3) Where a State agency is unable to adequately remove or remedy a conflict, it shall carry out the Ombudsman program by contract or other arrangement with a public agency or nonprofit private organization, pursuant to section 712(a)(4) of the Act. The State agency may not enter into a contract or other arrangement to carry out the Ombudsman program if the other entity, and may not operate the Office directly if it” to remove the erroneous phrase “if the other entity.” 45 CFR 1324.21(b)(3) contains a grammatical typo. The earlier version at **Federal Register** Number 2015–01914, July 1, 2016 was referred to identify the correct grammatical language.

#### 45 CFR Part 1325

- *Correct Reference.* In § 1325.4, this rule removes the incorrect reference to 45 CFR 1386.30 and replaces it with the correct reference 45 CFR 1326.30(f). 45 CFR 1386 was moved to 45 CFR 1326 in 2016 by 81 FR 35644 reflecting the Administration for Community Living’s 2012 reorganization in a single subchapter of the regulations. The text of statutes was not completely updated to align with this final rule.

#### 45 CFR Part 1326

- *Correct Heading.* In 45 CFR 1326, this rule removes the incorrect heading of “Formula Grant Program” and replaces it with the correct heading “Developmental Disabilities Formula Grant Programs”. This heading was changed in 2016 by 81 FR 35644 reflecting the Administration for Community Living’s 2012 reorganization in a single subchapter of the regulations. The text of statutes was not completely updated to align with this final rule.

- *Correct Reference.* In § 1326.103, this rule removes the incorrect reference to 45 CFR 1386.90 and replaces it with the correct reference 45 CFR 1326.90. 45 CFR 1386 was moved to 45 CFR 1326

in 2016 by 81 FR 35644 reflecting the Administration for Community Living's 2012 reorganization in a single subchapter of the regulations. The text of statutes was not completely updated to align with this final rule.

- *Correct Reference.* In § 1326.112, this rule removes the incorrect reference to 45 CFR 1386.84 and replaces it with the correct reference 45 CFR 1326.84. 45 CFR 1386 was moved to 45 CFR 1326 in 2016 by 81 FR 35644 reflecting the Administration for Community Living's 2012 reorganization in a single subchapter of the regulations. The text of statutes was not completely updated to align with this final rule.

- *Correct Reference.* In § 1326.93, this rule removes the incorrect reference to 45 CFR 1386.94 and replaces it with the correct reference 45 CFR 1326.94. 45 CFR 1386 was moved to 45 CFR 1326 in 2016 by 81 FR 35644 reflecting the Administration for Community Living's 2012 reorganization in a single subchapter of the regulations. The text of statutes was not completely updated to align with this final rule.

#### 45 CFR Part 1328

- *Correct Reference.* In § 1328.2, this rule removes the incorrect reference to 45 CFR 1385.3 and replaces it with the correct reference 45 CFR 1325.3; removes the incorrect reference to 45 CFR 1388.3 and replaces it with the correct reference 45 CFR 1328.3; and removes the incorrect reference to 45 CFR 1388.4 and replaces it with the correct reference to 45 CFR 1328.4. 45 CFR 1385 was moved to 45 CFR 1325 and 45 CFR 1388 was moved to 45 CFR 1328 in 2016 by 81 FR 35644 reflecting the Administration for Community Living's 2012 reorganization in a single subchapter of the regulations. The text of statutes was not completely updated to align with this final rule.

- *Correct Reference.* In § 1328.3, this rule removes the incorrect reference to 45 CFR 1388.2 and replaces it with the correct reference 45 CFR 1328.2. 45 CFR 1388 was moved to 45 CFR 1386 in 2016 by 81 FR 35644 reflecting the Administration for Community Living's 2012 reorganization in a single subchapter of the regulations. The text of statutes was not completely updated to align with this final rule.

- *Correct Reference.* In § 1328.5, this rule removes the incorrect reference to 45 CFR 1385.3 and replaces it with the correct reference 45 CFR 1325.3; removes the incorrect reference to 45 CFR 1388.2 and replaces it with the correct reference 45 CFR 1328.2; removes the incorrect reference to 45 CFR 1388.3 and replaces it with the correct reference to 45 CFR 1328.3. 45

CFR 1385 was moved to 45 CFR 1325 and 45 CFR 1388 was moved to 45 CFR 1328 in 2016 by 81 FR 35644 reflecting the Administration for Community Living's 2012 reorganization in a single subchapter of the regulations. The text of statutes was not completely updated to align with this final rule.

#### 48 CFR Part 302

- *Correct Reference.* In § 302.101, this rule removes the incorrect reference to 48 CFR 301.604 and replaces it with the correct reference PGI Part 301.604.

#### 48 CFR Part 326

- *Correct Reference.* In § 326.603(d), this rule removes the incorrect reference to '326.2' and replaces it with '326.6'. This change is not substantive as it only reflects the renumbering of the reference and the content has not been changed.

### IV. Rulemaking Procedure

Under the Administrative Procedure Act (5 U.S.C. 553(b)), an agency may waive publication in the **Federal Register** of a notice of proposed rulemaking and opportunity for comment requirements if it finds, for good cause, that they are impractical, unnecessary, or contrary to the public interest. As authorized by 5 U.S.C. 553(b)(3)(B), HHS finds good cause to waive notice and opportunity for comment on these amendments, as notice and opportunity for comment are unnecessary. These amendments will have no substantive impact and are of an administrative nature as they deal with correcting incorrect references and misspellings. HHS is exercising its authority under 5 U.S.C. 553(b)(3)(B) to publish these amendments as a final rule. The amendments are effective 30 days after date of publication in the **Federal Register**. These amendments do not require action by any person or entity regulated by HHS, and do not change the substantive responsibilities of any person or entity regulated by HHS.

### V. Executive Orders 12866, 13563, 13771, and 13777

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity).

Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as "any regulatory action that is likely to result in a rule that may: (1) Have an

annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in th[e] Executive Order."

A regulatory impact analysis must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). HHS submits that this final rule is not economically significant as measured by the \$100 million threshold, and hence not a major rule under the Congressional Review Act. This rule has not been designated as a significant regulatory action as defined by Executive Order 12866. As such, it has not been reviewed by the Office of Management and Budget.

Executive Order 13771, titled "Reducing Regulation and Controlling Regulatory Costs," was issued on January 30, 2017. It has been determined that this rule is not significant and thus is exempt from regulatory or deregulatory action for the purposes of Executive Order 13771.

On February 24, 2017, the President issued Executive Order 13777 titled "Enforcing the Regulatory Reform Agenda". As required by Section 3 of the Executive Order, HHS established a Regulatory Reform Task Force (HHS Task Force) to review existing regulations and make recommendations regarding their repeal, replacement, or modification. It has been determined that this rule is not significant and thus is exempt for the purposes of Executive Order 13777.

### VI. Regulatory Flexibility Act

This action will not have a significant impact on a substantial number of small entities. Therefore, the regulatory flexibility analysis provided for under the Regulatory Flexibility Act is not required.

### VII. Paperwork Reduction Act

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## VIII. Federalism

We have analyzed this final rule in accordance with the principles set forth in E.O. 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

### List of Subjects

#### *2 CFR Part 376*

Administrative practice and procedure, Grant programs, Reporting and recordkeeping requirements.

#### *21 CFR Part 1*

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

#### *21 CFR Part 5*

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

#### *21 CFR Part 12*

Administrative practice and procedure.

#### *21 CFR Part 14*

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

#### *21 CFR Part 25*

Environmental impact statements, Foreign relations, Reporting and recordkeeping requirements.

#### *21 CFR Part 81*

Color additives, Cosmetics, Drugs.

#### *21 CFR Part 133*

Cheese, Food grades and standards, Food labeling.

#### *21 CFR Part 172*

Food Additives, Reporting and recordkeeping requirements.

#### *21 CFR Part 178*

Food additives, Food packaging.

#### *21 CFR Part 184*

Food Additives.

#### *21 CFR Part 201*

Drugs, Labeling, Reporting and recordkeeping requirements.

#### *21 CFR Part 310*

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

#### *21 CFR Part 369*

Labeling, Medical devices, Over-the-counter drugs.

#### *21 CFR Part 501*

Animal foods, Packaging and containers, Reporting and recordkeeping requirements.

#### *21 CFR Part 582*

Animal feeds, Animal foods, Food additives.

#### *42 CFR Part 23*

Government employees, Health professions, Loan programs-health, Manpower, Reporting and recordkeeping requirements.

#### *42 CFR Part 51c*

Grant programs-health, Health care, Health facilities, Reporting and recordkeeping requirements.

#### *42 CFR Part 52i*

Grant programs-health, Medical research.

#### *42 CFR Part 56*

Grant programs-health, Health care, Health facilities, Migrant labor, Reporting and recordkeeping requirements.

#### *42 CFR Part 57*

Aged, Education of disadvantaged, Educational facilities, Educational study programs, Grant programs-education, Grant programs-health, Health facilities, Health professions, Loan programs-health, Medical and dental schools, Reporting and recordkeeping requirements, Scholarships and fellowships, Student aid.

#### *42 CFR Part 63*

Grant programs-health, Health professions, Libraries, Manpower training programs, Student aid.

#### *42 CFR Part 124*

Grant programs-health, Health facilities, Reporting and recordkeeping requirements.

#### *42 CFR Part 411*

Diseases, Medicare, Reporting and recordkeeping requirements.

#### *42 CFR Part 412*

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

#### *42 CFR Part 422*

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

#### *42 CFR Part 423*

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

#### *42 CFR Part 426*

Administrative practice and procedure, Medicare, Reporting and recordkeeping requirements.

#### *42 CFR Part 440*

Grant programs-health, Medicaid.

#### *42 CFR Part 441*

Aged, Family planning, Grant programs-health, Infants and children, Medicaid, Penalties, Reporting and recordkeeping requirements.

#### *42 CFR Part 447*

Accounting, Administrative practice and procedure, Drugs, Grant programs-health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

#### *42 CFR Part 482*

Grant programs-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirement.

#### *42 CFR Part 485*

Grant programs-health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

#### *42 CFR Part 1004*

Administrative practice and procedure, Health facilities, Health professions, Medicare, Peer Review Organization (PRO), Penalties, Reporting and recordkeeping requirements.

#### *42 CFR Part 1008*

Administrative practice and procedure, Medicaid, Medicare, Reporting and recordkeeping requirements.

#### *45 CFR Part 3*

Federal buildings and facilities, Penalties, Traffic regulations.

#### *45 CFR Part 63*

Grant programs-communications, Grant programs-education, Grant

programs-health, Grant programs-social programs, Research, Telecommunications.

#### 45 CFR Part 75

Accounting, Administrative practice and procedure, Adult education, Aged, Agriculture, American Samoa, Bilingual education, Blind, Business and industry, Civil rights, Colleges and universities, Communications, Community development, Community facilities, Copyright, Credit, Cultural exchange programs, Educational facilities, Educational research, Education, Education of disadvantaged, Education of individuals with disabilities, Educational study programs, Electric power, Electric power rates, Electric utilities, Elementary and secondary education, Energy conservation, Equal educational opportunity, Federally affected areas, Government contracts, Grant programs, Grant programs-agriculture, Grant programs-business, Grant programs-communications, Grant programs-education, Grant programs-energy, Grant programs-health, Grant programs-housing and community development, Grant programs-social programs, Grants administration, Guam, Home improvement, Homeless, Hospitals, Housing, Human research subjects, Indians, Indians-education, Infants and children, Insurance, Intergovernmental relations, International organizations, Inventions and patents, Loan programs, Loan programs social programs, Loan programs-agriculture, Loan programs-business, Loan programs-communications, Loan programs-energy, Loan programs-health, Loan programs-housing and community development, Manpower training programs, Migrant labor, Mortgage insurance, Nonprofit organizations, Northern Mariana Islands, Pacific Islands Trust Territories, Privacy, Renewable Energy, Reporting and recordkeeping requirements, Rural areas, Scholarships and fellowships, School construction, Schools, Science and technology, Securities, Small businesses, State and local governments, Student aid, Teachers, Telecommunications, Telephone, Urban areas, Veterans, Virgin Islands, Vocational education, Vocational rehabilitation, Waste treatment and disposal, Water pollution control, Water resources, Water supply, Watersheds, Women.

#### 45 CFR Part 305

Accounting, Child support, Grant programs-social programs, Reporting and recordkeeping requirements.

#### 45 CFR Part 307

Child support, Computer technology, Grant programs-social programs, Reporting and recordkeeping requirements.

#### 45 CFR Parts 1324, 1325, 1326, and 1328

Administrative practice and procedure, Aged, Colleges and universities, Grant programs-Education, Grant programs-Indians, Grant programs-social programs, Indians, Individuals with disabilities, Legal services, Long term care, Nutrition, Research, Reporting and recordkeeping requirements.

#### 48 CFR Parts 302 and 326

Government procurement.

For reasons described in the preamble, the Department of Health and Human Services amends 2 CFR part 376; 21 CFR parts 1, 5, 12, 14, 25, 81, 133, 172, 178, 184, 201, 310, 369, 501, and 582; 42 CFR parts 23, 51c, 52i, 56, 57, 63, 124, 411, 412, 422, 423, 426, 440, 441, 447, 482, 485, 1004, and 1008; 45 CFR parts 3, 63, 75, 305, 307, 1324, 1325, 1326, and 1328; and 48 CFR parts 302 and 326 as follows:

#### Title 2—Grants and Agreements

##### PART 376—NONPROCUREMENT DEBARMENT AND SUSPENSION

■ 1. The authority citation for part 376 continues to read as follows:

**Authority:** 5 U.S.C. 301; 31 U.S.C. 6101 (note); E.O. 12689, 3 CFR, 1989 Comp., p. 235; E.O. 12549, 3 CFR, 1986 Comp., p. 198; E.O. 11738, 3 CFR, 1973 Comp., p. 799.

##### § 376.10 [Amended]

■ 2. Amend § 376.10 as follows:

■ a. Remove the reference “(3 CFR 1986 Comp., p. 189)”;

■ b. Remove the reference “(3 CFR 1989 Comp., p. 235)”.

#### Title 21—Food and Drugs

##### PART 1—GENERAL ENFORCEMENT REGULATIONS

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

**Authority:** 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350e, 350j, 350k, 352, 355, 360b, 360ccc, 360ccc-1, 360ccc-2, 362, 371, 373, 374, 379j-31, 381, 382, 384a, 384b, 384d, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271; Pub. L. 107-188, 116 Stat. 594, 668-69; Pub. L. 111-353, 124 Stat. 3885, 3889.

##### § 1.24 [Amended]

■ 4. Amend § 1.24(a)(6)(ii) and (8)(ii) by removing the reference “§ 101.105(j)” and adding in its place the reference “§ 101.7”.

#### PART 5—ORGANIZATION

■ 5. The authority citation for part 5 continues to read as follows:

**Authority:** 5 U.S.C. 552; 21 U.S.C. 301-397.

##### § 5.1100 [Amended]

■ 6. Amend § 5.1100 by

##### § 5.1105 [Amended]

■ 7. Revise § 5.1105 to read as follows:

##### § 5.1105 Chief Counsel, Food and Drug Administration.

The Office of the Chief Counsel’s mailing address is White Oak Bldg. 1, 10903 New Hampshire Ave., Silver Spring, MD 20993.<sup>1</sup>

#### PART 12—FORMAL EVIDENTIARY PUBLIC HEARING

■ 8. The authority citation for part 12 continues to read as follows:

**Authority:** 21 U.S.C. 141-149, 321-393, 467f, 679, 821, 1034; 42 U.S.C. 201, 262, 263b-263n, 264; 15 U.S.C. 1451-1461; 5 U.S.C. 551-558, 701-721; 28 U.S.C. 2112.

##### § 12.21 [Amended]

■ 9. Amend § 12.21(a)(2) by removing the phrase “514.2 for applications for animal feeds”.

#### PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

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

**Authority:** 5 U.S.C. App. 2; 15 U.S.C. 1451-1461, 21 U.S.C. 41-50, 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107-109; Pub. L. 108-155; Pub. L. 113-54.

##### § 14.7 [Amended]

■ 11. Amend § 14.7(b) by removing “45 CFR 5.34” and add in its place “45 CFR 5.61—and 45 CFR 5.64”.

#### PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

■ 12. The authority citation for part 25 continues to read as follows:

**Authority:** 21 U.S.C. 321-393; 42 U.S.C. 262, 263b-264; 42 U.S.C. 4321, 4332; 40 CFR

<sup>1</sup> The Office of the Chief Counsel (also known as the Food and Drug Division, Office of the General Counsel, Department of Health and Human Services), while administratively within the Office of the Commissioner, is part of the Office of the General Counsel of the Department of Health and Human Services.



1500–1508; E.O. 11514, 35 FR 4247, 3 CFR, 1971 Comp., p. 531–533 as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1978 Comp., p. 123–124; E.O. 12114, 44 FR 1957, 3 CFR, 1980 Comp., p. 356–360.

**§ 25.33 [Amended]**

- 13. Amend § 25.33 by removing paragraph (a)(7).
- 14. Amend § 25.33 by revising paragraph (a)(5) and (6) to read as follows:

**§ 25.33 Animal drugs.**

\* \* \* \* \*

(a) \* \* \*

- (5) A change of sponsor; or
- (6) A previously approved animal drug to be contained in medicated feed blocks under § 510.455 of this chapter or as a liquid feed supplement under § 558.5 of this chapter.

\* \* \* \* \*

**PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS**

- 15. The authority citation for part 81 continues to read as follows:  
*Authority:* 21 U.S.C. 371, 379e, 379e note.

**§ 81.30 [Amended]**

- 16. Amend § 81.30(s)(2) by removing the last sentence.

**§ 81.32 [Removed]**

- 17. Remove § 81.32.

**PART 133—CHEESES AND RELATED CHEESE PRODUCTS**

- 18. The authority citation for part 133 continues to read as follows:  
*Authority:* 21 U.S.C. 321, 341, 343, 348, 371, 379e.

**§ 133.116 [Amended]**

- 19. Remove § 133.116(d).

**§ 133.121 Amended]**

- 20. Remove § 133.121(f).

**PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION**

- 21. The authority citation for part 172 continues to read as follows:  
*Authority:* 21 U.S.C. 321, 341, 342, 348, 371, 379e.
- 22. Revise § 172.840(c)(13) to read as follows:

**§ 172.840 Polysorbate 80.**

\* \* \* \* \*

(c) \* \* \*

(13) As a defoaming agent in the preparation of the creaming mixture for cottage cheese as identified in § 133.128 of this chapter, whereby the amount of the additive does not exceed .008 percent by weight of the finished product.

\* \* \* \* \*

**PART 178—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION**

- 23. The authority citation for part 178 continues to read as follows:

*Authority:* 21 U.S.C. 321, 342, 348, 379e.

- 24. Revise § 178.3730 to read as follows:

**§ 178.3730 Piperonyl butoxide and pyrethrins as components of bags.**

Piperonyl butoxide in combination with pyrethrins may be safely used for insect control on bags that are intended for use in contact with dried feed or dried food in compliance with 40 CFR 180.127 and 40 CFR 180.128.

**PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE**

- 25. The authority citation for part 184 continues to read as follows:

*Authority:* 21 U.S.C. 321, 342, 348, 371.

- 26. Revise § 184.1097(c)(2) to read as follows:

**§ 184.1097 Tannic acid.**

\* \* \* \* \*

(c) \* \* \*

(2) Tannic acid may be used in rendered animal fat in accordance with 9 CFR 424.21.

\* \* \* \* \*

- 27. Revise § 184.1143(d) to read as follows:

**§ 184.1143 Ammonium sulfate.**

\* \* \* \* \*

(d) The ingredient is used in food at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1). Current good manufacturing practice results in a maximum level, as served, of 0.15 percent for baked goods as defined in § 170.3(n)(1) of this chapter and 0.1 percent for gelatins and puddings as defined in § 170.3(n)(22) of this chapter.

\* \* \* \* \*

- 28. Revise § 184.1924(c)(1) to read as follows:

**§ 184.1924 Urease enzyme preparation from Lactobacillus fermentum.**

\* \* \* \* \*

(c) \* \* \*

(1) The ingredient is used in wine, as defined in 27 CFR 1.10 and 4.10, as an enzyme as defined in § 170.3(o)(9) of this chapter to convert urea to ammonia and carbon dioxide.

\* \* \* \* \*

**PART 201—LABELING**

- 29. The authority citation for part 201 continues to read as follows:

*Authority:* 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

- 30. Revise § 201.317(c) to read as follows:

**§ 201.317 Digitalis and related cardiotonic drugs for human use in oral dosage forms; required warning.**

\* \* \* \* \*

(c) This section does not apply to digoxin products for oral use.

**PART 310—NEW DRUGS**

- 31. The authority citation for part 310 continues to read as follows:

*Authority:* 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360hh–360ss, 361(a), 371, 374, 375, 379e, 379k–l; 42 U.S.C. 216, 241, 242(a), 262.

**§ 310.303 [Removed]**

- 32. Remove § 310.303.

**PART 369—INTERPETATIVE STATEMENT RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE**

- 33. The authority citation for part 369 continues to read as follows:

*Authority:* 21 U.S.C. 321, 331, 351, 352, 353, 355, 371.

- 34. Revise § 369.3 to read as follows:

**§ 369.3 Warnings required on drugs exempted from prescription-dispensing requirements of section 503(b)(1)(C).**

Drugs exempted from prescription-dispensing requirements under section 503(b)(1)(C) of the act are subject to the labeling requirements prescribed in § 310.201(a) of this chapter. Although, for convenience, warning and caution statements for a number of the drugs named in § 310.201 of this chapter (cross-referenced in the text of this part) are included in subpart B of this part, the inclusion of such drugs in §§ 369.20 or 369.21 in no way affects the requirements for compliance with § 310.201(a) of this chapter, or the provisions of an effective application pursuant to section 505(b) of the act.

**PART 501—ANIMAL FOOD LABELING**

■ 35. The authority citation for part 501 continues to read as follows:

**Authority:** 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

■ 36. Amend § 501.105, by revising the introductory text of paragraph (t) to read as follows:

**§ 501.105 Declaration of net quantity of contents when exempt.**

\* \* \* \* \*

(t) Where the declaration of net quantity of contents is in terms of net weight and/or drained weight or volume and does not accurately reflect the actual quantity of the contents or the product falls below the applicable standard of fill of container because of equipment malfunction or otherwise unintentional product variation, and the label conforms in all other respects to the requirements of this chapter, the mislabeled food product may be sold by the manufacturer or processor directly to institutions operated by Federal, State or local governments: *Provided*, That:

\* \* \* \* \*

**PART 582—SUBSTANCES GENERALLY RECOGNIZED AS SAFE**

■ 37. The authority citation for part 582 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 348, 371.

■ 38. Revise § 582.99 to read as follows:

**§ 582.99 Adjuvants for pesticide chemicals.**

Adjuvants, identified and used in accordance with 40 CFR 180.910 and 180.920, which are added to pesticide use dilutions by a grower or applicator prior to application to the raw agricultural commodity, are exempt from the requirement of tolerances under section 409 of the act.

**Title 42—Public Health****PART 23—NATIONAL HEALTH SERVICE CORPS**

■ 39. The authority citation for part 23 currently reads as follows:

**Authority:** 42 U.S.C. 254f, 254f–1, 254g, 254h, 254h–1, 254p(c), and 254n(e)(1).

**§ 23.9 [Amended]**

■ 40. Revise § 23.9(c)(1) to read as follows:

**§ 23.9 What must an entity to which National Health Service Corps personnel are assigned (i.e., a National Health Service Corps site) charge for the provision of health services by assigned personnel?**

\* \* \* \* \*

(c)(1) No charge or a nominal charge will be made for health services provided by assigned National Health Service Corps personnel to individuals within the health manpower shortage area with annual incomes at or below the poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2). However, no individual will be denied health services based upon inability to pay for the services. Any individual who has an annual income above the poverty guidelines but whose income does not exceed 200 percent of the poverty guidelines, will receive health services at a nominal charge. However, charges will be made for services to the extent that payment will be made by a third party which is authorized or under legal obligation to pay the charges.

\* \* \* \* \*

**PART 51c—GRANTS FOR COMMUNITY HEALTH SERVICES**

■ 41. The authority citation for part 51c continues to read as follows:

**Authority:** 42 U.S.C. 216, 254c.

**§ 51c.107 [Amended]**

■ 42. Amend § 51c.107(b)(5) by removing ‘the most recent CSA Income Poverty Guidelines’ (45 CFR 1060.2) issued by the Community Services Administration;” and adding in its place “the poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2);”.

**§ 51c.303 [Amended]**

■ 43. Amend § 51c.303(f) by removing the phrase “the most recent ‘CSA Poverty Income Guidelines’ (45 CFR 1060.2)” and adding in its place “the poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2);”.

**PART 52i—NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES RESEARCH ENDOWMENT PROGRAMS**

■ 44. The authority citation for part 52i continues to read as follows:

**Authority:** 42 U.S.C. 216, 285t–285t–1.

**§ 52i.11 [Amended]**

■ 45. Amend § 52i.11 by:

■ a. In paragraph (b), removing the reference “74.53” and adding in its place the reference “75.361”.

■ b. In paragraph(c), removing the reference “74.53e” and adding in its place the reference “75.364”.

■ c. In paragraph (d), removing the reference “74.52” and adding in its place the reference “75.341”.

**PART 56—GRANTS FOR MIGRANT HEALTH SERVICES**

■ 46. The authority citation for part 56 continues to read as follows:

**Authority:** U.S.C. 216, 247d.

**§ 56.108 [Amended]**

■ 47. Amend § 56.108 by removing the phrase “the most recent ‘CSA Income Poverty Guidelines’ (45 CFR 1060.2) issued by the Community Services Administration;” and replacing it with “the poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2);”.

**§ 56.303 [Amended]**

■ 48. Amend § 56.303(f) by removing the phrase “the most recent ‘CSA Poverty Income Guidelines’ (45 CFR 1060.2)” and adding in its place “the poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2);”.

**§ 56.603 [Amended]**

■ 49. Amend § 56.603 by removing the phrase “the most recent ‘CSA Poverty Income Guidelines’ (45 CFR 1060.2)” and adding in its place “the poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2);”.

**PART 57—GRANTS FOR CONSTRUCTION OF TEACHING FACILITIES, EDUCATIONAL IMPROVEMENTS, SCHOLARSHIPS AND STUDENT LOANS**

■ 50. The authority citation for part 57 continues to read as follows:

**Authority:** 42 U.S.C. 293g.

**§ 57.1505 [Amended]**

■ 51. Amend § 57.1505(a)(1) by removing the reference “57.110”.

**PART 63—TRAINEESHIPS**

■ 52. The authority citation for part 63 continues to read as follows:

**Authority:** 42 U.S.C. 216, 282(b)(13), 284(b)(1)(C), 285a–2(b)(3), 286b–3, 287c–21(a).

**§ 63.2 [Amended]**

■ 53. Amend § 63.2 by removing the reference “50.102” and adding in its place the reference “93.103”.

**§ 63.2 [Amended]**

■ 54. Amend § 63.2 by removing the phrase “Misconduct in science” and adding in its place “research misconduct”.

**§ 63.9 [Amended]**

■ 55. Amend § 63.9(b) by removing the phrase “misconduct in science” and add in its place “research misconduct”.

**PART 124—MEDICAL FACILITY CONSTRUCTION AND MODERNIZATION**

■ 56. The authority citation for part 124 continues to read as follows:

**Authority:** 42 U.S.C. 216, 300o–1, 300r, unless otherwise noted.

**§ 124.511 [Amended]**

■ 57. Amend § 124.511 by removing the reference “125.510”.

**§ 124.602 [Amended]**

■ 58. Amend § 124.602 by removing the reference “42 CFR 53.1(d)”.

**PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT**

■ 59. The authority citation for part 411 continues to read as follows:

**Authority:** 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

**§ 411.353 [Amended]**

■ 60. Amend § 411.353(d) by removing the reference “§ 1003.101 of this title” and adding in its place the reference “§ 1003.110”.

**PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES**

■ 61. The authority citation for part 412 continues to read as follows:

**Authority:** 42 U.S.C. 1302, 1395hh.

**§ 412.42 [Amended]**

■ 62. Amend § 412.42 as follows:

■ a. In paragraph (b)(2)(i), remove the reference “§ 405.310(g)” and add in its place “§ 411.15(g)”;

■ b. In paragraph (b)(2)(ii), remove the reference “§ 405.310(k)” and add in its place “§ 411.15(k)”;

■ c. In paragraph (b)(2)(iii), remove the reference “§ 405.310(m)” and add in its place “§ 411.15(m)”.

**PART 422—MEDICARE ADVANTAGE PROGRAM**

■ 63. The authority citation for part 422 continues to read as follows:

**Authority:** 42 U.S.C. 1302, 1395hh.

**§ 422.304 [Amended]**

■ 64. Amend § 422.304(f) by removing the reference “§ 495.220” and adding in its place “§ 495.204”.

**§ 422.322 [Amended]**

■ 65. Amend § 422.322(b) by removing the reference “413.86(d)” and adding in its place “413.76”.

**§ 422.324 [Amended]**

■ 66. Amend § 422.324(b)(2) by removing the reference “§ 413.86(b)” and adding in its place “§ 413.75(b)”.

**§ 422.1094 [Amended]**

■ 67. Amend § 422.1094(b)(2) by removing the reference “422.858” and adding in its place the reference “§ 423.1088 of this chapter”.

**PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT**

■ 68. The authority citation for part 423 continues to read as follows:

**Authority:** 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh.

**§ 423.1094 [Amended]**

■ 69. Amend § 423.1094(b)(2) by removing the reference “423.858” and adding in its place the reference “§ 423.1088”.

**§ 423.2330 [Amended]**

■ 70. Amend § 423.2330(c)(3) by removing the reference “§ 423.2306(b)(4) of this subpart” and adding in its place the reference “§ 423.2315(b)(4)”.

**PART 426—REVIEW OF NATIONAL COVERAGE DETERMINATIONS AND LOCAL COVERAGE DETERMINATIONS**

■ 71. The authority citation for part 426 continues to read as follows:

**Authority:** 42 U.S.C. 1302, 1395hh.

**§ 426.110 [Amended]**

■ 72. Amend § 426.110 in paragraph 1 of the definition of “Proprietary data and Privileged information” by removing the reference “45 CFR 5.65” and adding in its place “45 CFR 5.31(d) and (e)”.

**PART 440—SERVICES: GENERAL PROVISIONS**

■ 73. The authority citation for part 440 continues to read as follows:

**Authority:** 42 U.S.C. 1302.

**§ 440.20 [Amended]**

■ 74. Amend § 440.20(b) introductory text by removing the reference “§ 481.1” and adding in its place “§ 491.2”.

**PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES**

■ 75. The authority citation for part 441 continues to read as follows:

**Authority:** 42 U.S.C. 1302.

**§ 441.17 [Amended]**

■ 76. Amend § 441.17 as follows:

■ a. In paragraph (a)(1), remove the reference “§ 405.1316” and add in its place the reference “part 493”;

■ b. In paragraph (a)(4), remove the reference “§ 405.1128(a)” and add in its place the reference “part 493”; and

■ c. In paragraph (b), remove the reference “§ 405.1316(f)(2) and (3)” and add in its place the reference “part 493 of this chapter”.

**§ 441.18 [Amended]**

■ 77. Amend § 441.18(c) introductory text by removing the reference “§ 441.169” and adding in its place “§ 440.169”.

**PART 447—PAYMENTS FOR SERVICES**

■ 78. The authority citation for part 447 continues to read as follows:

**Authority:** 42 U.S.C. 1302, 1396r–8.

**§ 447.299 [Amended]**

■ 79. Amend § 447.299(c) introductory text by removing the reference “§ 455.204” and adding in its place “§ 455.304 of this chapter”.

**PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS**

■ 80. The authority citation for part 482 continues to read as follows:

**Authority:** 42 U.S.C. 1302, 1395hh, 1395rr, 1395lll, unless otherwise noted.

**§ 482.27 [Amended]**

■ 81. Amend § 482.27 as follows:

■ a. In paragraph (b)(3)(iii), remove the phrase “, as set forth at 21 CFR 610.48(b)(3)”;

■ b. In paragraph (b)(4)(iii), remove the reference “21 CFR 610.46(b)(2), 610.47(b)(2), and 610.48(c)(2)” and add in its place the reference “21 CFR 610.46(b)(2) and 610.47(b)(2)”.

**PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS**

■ 82. The authority citation for part 485 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395(hh).

**§ 485.639 [Amended]**

■ 83. Amend § 485.639(c)(1)(vii) by removing the reference “§ 413.86” and adding in its place the reference “§§ 413.76 through 413.83”.

**PART 1004—IMPOSITION OF SANCTIONS ON HEALTH CARE PRACTITIONERS AND PROVIDERS OF HEALTH CARE SERVICES BY A QUALITY IMPROVEMENT ORGANIZATION**

■ 84. The authority citation for part 1004 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320c–5.

**§ 1004.40 [Amended]**

■ 85. Amend § 1004.40 by removing the reference “476.139” and adding in its place “480.139”.

**PART 1008—ADVISORY OPINIONS BY THE OIG**

■ 86. The authority citation for part 1008 continues to read as follows:

Authority: 42 U.S.C. 1320a–7d(b).

**§ 1008.36 [Amended]**

■ 87. Amend § 1008.36 by removing the reference “45 CFR 5.65” and adding in its place “45 CFR 5.41”.

**Title 45—Public Welfare**

**PART 3—CONDUCT OF PERSONS AND TRAFFIC ON THE NATIONAL INSTITUTES OF HEALTH FEDERAL ENCLAVE**

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

Authority: 40 U.S.C. 318–318d, 486; Delegation of Authority, 33 FR 604.

**§ 3.1 [Amended]**

■ 89. In § 3.1, in the definition of “Police officer”, remove the reference “40 United States Code section 318 or 318d” and add in its place “U.S. Public Law 107–296, Homeland Security Act of 2002”.

**§ 3.2 [Amended]**

■ 90. In § 3.2, revise the table in paragraph (f) to read as follows:

**§ 3.2 Applicability.**

\* \* \* \* \*

(f) \* \* \*

Subject	Maryland code annotated	Provides generally	Maximum penalty
1. Pedestrian right-of-way .....	Transportation, Sec. 21–502 ..  Sec. 21–511 .....	Pedestrians have the right-of-way in crosswalks and certain other areas. Subject to certain limitations.  Blind, partially blind, or hearing impaired pedestrians have the right-of-way at any crossing or intersection. Subject to certain limitations.	Imprisonment 2 months and/or \$500 fine.  \$500 fine.
2. Drivers to exercise due care	Transportation, Sec. 21–504 ..	Drivers shall exercise due care to avoid colliding with pedestrians, children and incapacitated individuals.	\$500 fine.
3. Driving while intoxicated, under the influence of alcohol and/or a drug or controlled substance.	Transportation, Sec. 21–902 ..	Prohibits .....	Sec. 21–902(a) (driving while intoxicated, first offense): Imprisonment 1 year and/or \$1,000 fine. Sec. 21–902 (b), (c), (d) (driving under the influence): Imprisonment 2 months and/or \$500 fine.
4. Unattended motor vehicles ..	Transportation, Sec. 21–1101	Prohibits leaving motor vehicles unattended unless certain precautions are taken.	\$500 fine.
5. Carrying or wearing certain concealed weapons (other than handguns) or openly with intent to injure.	Sec. 4–202 .....	Prohibits, except for law enforcement personnel or as a reasonable precaution against apprehended danger.	Imprisonment 3 years or \$1,000 fine.
6. Unlawful wearing, carrying, or transporting a handgun, whether concealed or openly.	Sec. 4–202 .....	Prohibits except by law enforcement personnel or with permit.	First offense and no prior related offense: Imprisonment 3 years and/or \$2,500 fine.
7. Use of handgun or concealable antique firearm in commission of felony or crime of violence.	Sec. 4–204 .....	Prohibits .....	Imprisonment 20 years.
8. Disturbance of the peace .....	Sec. 6–409 .....	Prohibits acting in a disorderly manner in public places.	Imprisonment 30 days and/or \$500 fine.
9. Gambling .....	Sec. 12–102 .....	Prohibits betting, wagering and gambling, and certain games of chance (does not apply to vending or purchasing lottery tickets authorized under State law in accordance with approved procedures).	Sec. 240: Imprisonment one year and/or \$1,000 fine. Sec. 245: Imprisonment 2 years and/or \$100 fine.

**§ 3.5 [Amended]**

■ 91. In § 3.5:

■ a. Removing the reference “41 CFR part 101–48” and adding in its place “41 CFR 102”.

■ b. Removing the “41 CFR 101–45.304” and 101–48.305” and add in their place “41 CFR part “102–41”.

**§ 3.61 [Amended]**

■ 92. Amend § 3.61 by removing the reference “40 U.S.C. 318c” and adding in its place the reference “U.S. Public

Law 107–296, Homeland Security Act of 2002”.

**PART 63—GRANT PROGRAMS ADMINISTERED BY THE OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION**

■ 93. The authority citation for part 63 continues to read as follows:

**Authority:** Sec. 602, Community Services Act (42 U.S.C. 2942); sec. 1110, Social Security Act (42 U.S.C. 1310).

**§ 63.1 Amended]**

■ 94. Amend § 63.1 by:

- a. Removing “41 CFR 3–1.53” and adding in its place “45 CFR 75.201(a)”.
- b. Removing “41 CFR Chapters 1 and 3” and adding in its place “CFR Title 48, Chapter 3”.

**PART 75—UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR HHS AWARDS**

■ 95. The authority citation for part 75 continues to read as follows:

**Authority:** 5 U.S.C. 301.

**§ 75.372 Amended]**

■ 96. Amend § 75.372 by removing “through 75.390” and adding in its place “and 75.386”.

**PART 305—PROGRAM PERFORMANCE MEASURES, STANDARDS, FINANCIAL INCENTIVES, AND PENALTIES**

■ 97. The authority citation for part 305 continues to read as follows:

**Authority:** 42 U.S.C. 609(a)(8), 652(a)(4), 652(g), 658a, 1302.

**§ 305.0 Amended]**

■ 98. Amend § 305.0 by removing “Sections 305.40 through 305.42” with “Sections 305.40, 305.42”.

**PART 307—COMPUTERIZED SUPPORT ENFORCEMENT SYSTEMS**

■ 99. The authority citation for part 307 continues to read as follows:

**Authority:** 42 U.S.C. 652–658, 664, 666–669A, 1302.

**§ 307.5 Amended]**

■ 100. Amend § 307.5(d)(3) by removing the reference “305.99” and adding in its place “305.66”.

**PART 1324—ALLOTMENTS FOR VULNERABLE ELDER RIGHTS PROTECTION ACTIVITIES**

■ 101. The authority citation for part 1324 continues to read as follows:

**Authority:** 42 U.S.C. 3001 *et seq.*

**§ 1324.11 Amended]**

■ 102. Amend § 1324.11 by:

- a. Removing the reference “1327.13(e)” and adding in its place “1324.13(e)”.
- b. Removing all references “1327.19(b)(5) through (8)” and adding in their places “1324.19(b)(5) through (8)”.
- c.
- d. Removing the reference “1327.21” and adding in its place “1324.21”.

**§ 1324.15 Amended]**

■ 103. Amend § 1324.15 by:

- a. Removing the reference “1327.13(e)” and adding in its place “1324.13(e)”.
- b. Removing the reference “1327.13(g)” and adding in its place “1324.13(g)”.
- c. Removing the reference “1327.13(c)(2)” and adding in its place “1324.13(c)(2)”.

**§ 1324.19 Amended]**

■ 104. Amend § 1324.19 by removing the reference “1327.11(e)(3)” wherever it appears and adding in its place “1324.11(e)(3)”.

**§ 1324.21 Amended]**

■ 105. Amend § 1324.21(b)(3) by removing the phrase “if the other entity”.

**PART 1325—REQUIREMENTS APPLICABLE TO THE DEVELOPMENTAL DISABILITIES PROGRAM**

■ 106. The authority citation for part 1325 continues to read as follows:

**Authority:** 42 U.S.C. 15001 *et seq.*

**§ 1325.4 Amended]**

■ 107. Amend § 1325.4 by removing the reference “45 CFR 1386.30(f)” and adding in its place “45 CFR 1326.30(f)”.

**PART 1326—DEVELOPMENTAL DISABILITIES FORMULA GRANT PROGRAMS**

■ 108. The authority citation for part 1326 continues to read as follows:

**Authority:** 42 U.S.C. 15001 *et seq.*

■ 109. Revise the part heading to read as set forth above.

**§ 1326.103 Amended]**

■ 110. Amend § 1326.103 by removing the reference “1386.90” and adding in its place “1326.90”.

**§ 1326.93 Amended]**

■ 111. Amend § 1326.93 by removing the reference “1386.94” and adding in its place “1326.94”.

**§ 1326.112 Amended]**

■ 112. Amend § 1326.112 by removing the reference “1386.84” and adding in its place “1326.84”.

**PART 1328—THE NATIONAL NETWORK OF UNIVERSITY CENTERS FOR EXCELLENCE IN DEVELOPMENTAL DISABILITIES, EDUCATION, RESEARCH, AND SERVICE**

■ 113. The authority citation for part 1328 continues to read as follows:

**Authority:** 42 U.S.C. 15001 *et seq.*

**§ 1328.2 Amended]**

■ 114. Amend § 1328.2 by:

- a. Removing the reference “1385.3” and adding in its place “1325.3”.
- b. Removing the reference “1388.3” and adding in its place “1328.3”.
- c. Removing the reference “1388.4” and adding in its place “1328.4”.

**§ 1328.3 Amended]**

■ 115. Amend § 1328.3 by removing the reference “1388.2” and adding in its place “1328.2”.

**§ 1328.5 Amended]**

■ 116. Amend § 1328.5 by:

- a. Removing the reference “1385.3” and adding in its place “1325.3”.
- b. Removing the reference “1388.2” and adding in its place “45 CFR 1328.2”.
- c. Removing the reference “1388.2(a)(1) and (2)” and adding in its place “1328.2(a)(1) and (2)”.
- d. Removing the reference “1388.3” and adding in its place “1328.3”.

**Title 48—Federal Acquisition Regulations System**

**PART 302—DEFINITIONS OF WORDS AND TERMS**

■ 117. The authority citation for part 302 continues to read as follows:

**Authority:** 5 U.S.C. 301; 40 U.S.C. 121 (c)(2).

**§ 302.101 Amended]**

■ 118. Amend § 302.101 by removing the reference “301.604” and adding in its place “PGI Part 301.604”

**PART 326—OTHER SOCIOECONOMIC PROGRAMS**

■ 119. The authority for part 326 continues to read as follows:

**Authority:** 5 U.S.C. 301, 40 U.S.C. 121(c)(2).

**§ 326.603 Amended]**

■ 120. Amend § 326.603(d) by removing the reference “326.2” and adding in its place “326.6”.

Dated: September 25, 2020.

Alex M. Azar II,  
Secretary.

[FR Doc. 2020–21774 Filed 11–13–20; 8:45 am]

BILLING CODE 4151–17–P

## DEPARTMENT OF AGRICULTURE

### Office of the Secretary

#### 2 CFR Parts 415 and 416

#### Rural Utilities Service

#### 7 CFR Part 1780

#### National Institute of Food and Agriculture

#### 7 CFR Part 3430

#### Department of Agriculture Regulations for Grants and Agreements; Update of Citations

**AGENCY:** Office of the Secretary, Rural Utilities Service, National Institute of Food and Agriculture, and Office of the Chief Financial Officer, Department of Agriculture.

**ACTION:** Final rule.

**SUMMARY:** The Office of Management and Budget (OMB) revised sections of its Guidance for Grants and Agreements in August 2020. This final rule amends the regulations of several United States Department of Agriculture agencies to reflect the revised OMB guidance and make technical corrections to the Department's grants and agreements regulations.

**DATES:** Effective November 16, 2020.

**FOR FURTHER INFORMATION CONTACT:** Tyson Whitney, Office of the Chief Financial Officer, Director, Transparency and Accountability Reporting Division, United States Department of Agriculture, 1400 Independence Avenue SW, Washington, DC 20250–9011, 202–720–8978, [tyson.whitney@usda.gov](mailto:tyson.whitney@usda.gov).

**SUPPLEMENTARY INFORMATION:** The regulations in 2 CFR chapter IV set forth the United States Department of Agriculture's (USDA) regulations for grants and agreements. In a final rule published December 19, 2014 (79 FR 75982), USDA's Office of the Chief Financial Officer adopted 2 CFR part 200, along with an agency-specific addendum in a new 2 CFR part 400. The regulations in 2 CFR parts 415, 416, 418, and 422 were established. The regulations in 2 CFR chapter IV updated and replaced provisions that had previously been found in 7 CFR parts 3015, 3016, 3018, 3019, 3022, and 3052.

The regulations of several USDA agencies in title 7 refer to and cite the grants and agreements regulations. Following the publication of the various final rules establishing the regulations in 2 CFR chapter IV, those agencies updated their regulations so that they referred to the new grants and agreements regulations in title 2 rather than the predecessor regulations in title 7. As a result of the August 13, 2020, publication of the Office of Management and Budget's "Guidance for Grants and Agreements" (85 FR 49506), we have identified a number of instances where technical corrections are necessary. This final rule makes those technical corrections where needed.

#### Effective Date

This rule relates to internal agency management and makes various nonsubstantive changes to the regulations in titles 2 and 7 of the Code of Federal Regulations to make technical corrections to the Department's grants and agreements regulations. Accordingly, notice and other public procedure on this rule are unnecessary and contrary to the public interest. Therefore, pursuant to 5 U.S.C. 553, notice of proposed rulemaking and opportunity to comment are not required and this rule may be made effective less than 30 days after publication in the **Federal Register**. Further, since this rule relates to internal agency management, it is exempt from the provisions of Executive Orders 12866, 12988, and 13771. Finally, this action is not a rule as defined by the Regulatory Flexibility Act (5 U.S.C. 501) and, thus, is exempt from the provisions of that Act.

#### Paperwork Reduction Act

This final rule contains no new reporting, recordkeeping, or third-party disclosure requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

#### List of Subjects

##### 2 CFR Parts 415 and 416

Accounting, Administrative practice and procedure, Agriculture, Auditing, Business and industry, Colleges and universities, Community development, Cost principles, Economic development, Government contracts, Grants administration, Grant programs, Grant programs—housing and community development, Hospitals, Indians, Loan programs—agriculture, Nonprofit organizations, Reporting and recordkeeping requirements, Rural areas, State and local governments.

#### 7 CFR Part 1780

Community development, Community facilities, Grant programs—housing and community development, Loan programs—housing and community development, Reporting and recordkeeping requirements, Rural areas, Waste treatment and disposal, Water supply, Watersheds.

#### 7 CFR Part 3430

Administrative practice and procedure, Agriculture research, Education, Federal assistance.

Accordingly, 2 CFR parts 415 and 416 and 7 CFR parts 1780 and 3430 are amended as follows:

#### Title 2—[Amended]

#### PART 415—GENERAL PROGRAM ADMINISTRATIVE REGULATIONS

- 1. The authority citation for part 415 is revised to read as follows:

**Authority:** 5 U.S.C. 301; 31 U.S.C. 901–903; 7 CFR 2.28.

- 2. In § 415.1, paragraphs (a)(1) and (b)(10) are revised to read as follows:

#### § 415.1 Competition in the awarding of discretionary grants and cooperative agreements.

(a) \* \* \*

(1) Potential applicants must be invited to submit proposals through publications such as the **Federal Register**, OMB-designated governmentwide website as described in 2 CFR 200.204, professional trade journals, agency or program handbooks, the Assistance Listings, or any other appropriate means of solicitation. In so doing, awarding agencies should consider the broadest dissemination of project solicitations in order to reach the highest number of potential applicants.

\* \* \* \* \*

(b) \* \* \*

(10) The Assistance Listings number and title.

\* \* \* \* \*

#### PART 416—GENERAL PROGRAM ADMINISTRATIVE REGULATIONS FOR GRANTS AND COOPERATIVE AGREEMENTS TO STATE AND LOCAL GOVERNMENTS

- 3. The authority citation for part 416 is revised to read as follows:

**Authority:** 5 U.S.C. 301; 31 U.S.C. 901–903; 7 CFR 2.28.

#### § 416.1 [Amended]

- 4. Section 416.1 is amended as follows:

- a. In paragraph (a), by removing the citation “2 CFR 200.101(e)(4) through