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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Administration for Children and Families

Administration for Community Living

Agency for Healthcare Research and Quality

Centers for Disease Control and Prevention

Centers for Medicare & Medicaid Services

Health Resources and Services Administration

Indian Health Service

Substance Abuse and Mental Health Services Administration

42 CFR Part 22

Rotational Program for Directors of Centers and other Components of HHS

AGENCY: The Department of Health and Human Services (HHS or the Department), and the following operating divisions: Administration for Children and Families (ACF); Administration for Community Living (ACL); Agency for Healthcare Research and Quality (AHRQ); Centers for Disease Control and Prevention (CDC); Centers for Medicare & Medicaid Services (CMS); Food and Drug Administration (FDA); Health Resources and Services Administration (HRSA); Indian Health Service (IHS); and Substance Abuse and Mental Health Services Administration (SAMHSA) (collectively the “Operating Divisions”).

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services issue this final rule to institute term limits for the Directors of centers, offices, bureaus, divisions, or administrations within the Department's Operating Divisions. This final rule will increase the potential for advancement within these agencies, which will in turn allow for the potential for fresh perspectives and allow the Department to better attract and retain personnel. Directors can be reappointed at the end of their terms, or reassigned with the agency if they are not.

DATES: This regulation is effective [30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION:

I. Objective

HHS, including its Operating Divisions, exists to serve the American people. The public is entitled to agencies that are responsive to the needs of—and accounts for the voices and experiences of—all Americans. Moreover, in order to fulfill its public-oriented mission, the Department needs to attract and retain competent officials. Sometimes center and other Directors at the Department serve in their positions for many years. While this can be beneficial in many circumstances, it reduces the opportunity and incentive for hard-working, competent, public-spirited officials at the level(s) below Director to rise within the agency. This final rule will increase the opportunity and incentive for Department officials to rise within their agencies.

In 2016, Congress enacted the 21st Century Cures Act, Pub. L. 114-255 (Dec. 13, 2016) (Act). Among other things, the Act provided that, other than the Director of the National Cancer Institute, Directors of national research institutes or national centers within the National Institutes of Health (NIH) shall be appointed to five-year terms, with the opportunity to be reappointed at the end of their terms.¹ In 2019, NIH announced that the 272 lab and branch chiefs who oversee NIH's intramural research

¹ Sec. 2033 of the Act, 42 U.S.C. 284.

would be limited to 12-year terms. At the time, the chair of NIH's equity committee, which pushed for the changes, explained that "[p]eople feel like there's no way they'll ever have a leadership position."²

The same concern applies to other operating divisions within HHS, where high-ranking officials sometimes remain in the same positions for many years. The Department wants those employees who are performing well to have the opportunity to advance within their agency. At the same time, under this final rule, if a center or other Director is performing well, he or she can be reappointed at the end of his or her term. By providing term limits, this final rule also opens up new avenues for advancement for existing Department personnel and those outside the Federal Government. In addition, term limits increase the potential to add diversity of background, experience, and thought to the leadership ranks at the Operating Divisions.

II. Legal Basis

The Department issues this final rule pursuant to 5 U.S.C. 301, which provides that the "head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property." This statute authorizes an "agency to regulate its own affairs," and issue rules, such as this one, that are "rules of agency organization [,] procedure or practice." *Chrysler Corp. v. Brown*, 441 U.S. 281, 309-10 (1979).

The requirements for notice and comment prior to finalization do not apply to this rule. 5 U.S.C. 553(a)(2) provides that the requirement for notice-and-comment prior to issuing a final rule does not apply to a "matter relating to agency management or personnel." Because this final rule merely provides for term limits for certain HHS officials, it is a matter relating to agency management or personnel and is exempt from the requirement for notice-and-comment.

² Jocelyn Kaiser, Shake-up at NIH: Term limits for important positions would open new opportunities for women, minorities, SCIENCE (May 2, 2019), *available at* <https://www.sciencemag.org/news/2019/05/shakeup-nih-term-limits-important-positions-would-open-new-opportunities-women>.

III. Provisions of Final Rule

This final rule adds nearly identical provisions to titles 21 and 42. The provisions added to title 21 provide for term limits for certain FDA officials, whereas the provisions added to title 42 provide for term limits for officials within the remaining Operating Divisions. Because the provisions and rationales are generally similar, below we generally discuss only the title 21 provisions. We also discuss the title 42 provisions where they differ from those added to title 21.

21 CFR 5.1115(a)

Section 5.1115(a) defines certain terms used in this final rule.

Section 5.1115(a)(1)

Section 5.1115(a)(1) provides that “Director” shall refer to:

- i. The Director of the Center for Biologics Evaluation and Research,
- ii. The Director of the Center for Devices and Radiological Health,
- iii. The Director of the Center for Drug Evaluation and Research,
- iv. The Director of the Center for Food Safety and Applied Nutrition,
- v. The Director of the Center for Tobacco Products,
- vi. The Director of the Center for Veterinary Medicine, and
- vii. The Director of the Oncology Center of Excellence.

42 CFR 22.2(a) (the title 42 equivalent that applies to Operating Divisions other than FDA) provides that “Director” within the Administration for Families and Children (ACF) shall refer to:

- i. The Director of the Office of Human Services Emergency Preparedness and Response and
- ii. The Director of Office on Trafficking in Persons.

42 CFR 22.2(a) provides that “Director” within the Administration for Community Living (ACL) shall refer to:

- i. The Deputy Administrator of the Center for Innovation and Partnership;

- ii. The Director of the Center for Policy and Evaluation; and
- iii. The Director of the National Institute on Disability, Independent Living, and Rehabilitation Research.

42 CFR 22.2(a) provides that “Director” within the Agency for Healthcare Research and Quality (AHQR) shall refer to:

- i. The Director of the Center for Financing, Access and Cost Trends;
- ii. The Director of the Center for Evidence and Practice Improvement;
- iii. Director of the Office of Extramural Research, Research, Education, and Priority Populations; and
- iv. The Director Center of the Quality Improvement and Patient Safety.

42 CFR 22.2(a) provides that “Director” within the Centers for Disease Control and Prevention (CDC) shall refer to:

- i. The Director of the Center for Global Health;
- ii. The Director of the Center for Preparedness and Response;
- iii. The Director of the Center for State, Tribal, Local, and Territorial Support;
- iv. The Director of the Center for Surveillance, Epidemiology, and Laboratory Services;
- v. The Director of the National Center for Health Statistics;
- vi. The Director of the National Center on Birth Defects and Developmental Disabilities;
- vii. The Director of the National Center for Chronic Disease Prevention and Health Promotion;
- viii. The Director of the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry;
- ix. The Director of the National Center for Injury Prevention and Control;
- x. The Director of the National Center for Immunization and Respiratory Diseases;
- xi. The Director of the National Center for Emerging and Zoonotic Infectious Diseases;

- xii. The Director of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention;
- xiii. The Director of the Agency for Toxic Substances and Disease Registry (ATSDR) Office of Management and Analytics;
- xiv. The Director of the ATSDR Division of Environmental Health Science and Practice;
- xv. The Director of the ATSDR Office of Policy, Planning, and Partnerships;
- xvi. The Associate Director of the ATSDR Office of Science; and
- xvii. The Director of the ATSDR Division of Laboratory Sciences.

42 CFR 22.2(a) provides that “Director” within the Centers for Medicare & Medicaid Services (CMS) shall refer to:

- i. The Deputy Directors of the Center for Clinical Standards and Quality;
- ii. The Deputy Directors of the Center for Medicare and Medicaid Innovation;
- iii. The Deputy Directors of the Center for Medicare;
- iv. The Deputy Directors of the Center for Medicaid and CHIP Services;
- v. The Deputy Directors of the Center for Program Integrity; and
- vi. The Deputy Directors of the Center for Consumer Information and Insurance Oversight.

42 CFR 22.2(a) provides that “Director” within the Health Resources and Services Administration (HRSA) shall refer to:

- i. The Director of the Office of Global Health;
- ii. The Director of the Office of Health Equity;
- iii. The Director of the Office of Planning, Analysis and Evaluation;
- iv. The Director of the Office of Civil Rights, Diversity, and Inclusion;
- v. The Director of the Office of Women’s Health;
- vi. The Associate Administrator of the Maternal and Child Health Bureau;

- vii. The Associate Administrator of the HIV/AIDS Bureau;
- viii. The Associate Administrator of the Healthcare Systems Bureau;
- ix. The Associate Administrator of the Federal Office of Rural Health Policy;
- x. The Associate Administrator of the Bureau of Primary Health Care;
- xi. The Associate Administrator of the Bureau of Health Workforce; and
- xii. The Associate Administrator of the Office of Federal Assistance Management.

42 CFR 22.2(a) provides that “Director” within the Indian Health Service (IHS) shall refer to:

- i. The Director of the Office of Direct Service and Contracting Tribes;
- ii. The Director of the Office of Tribal Self Governance;
- iii. The Director of the Office of Urban Indian Health Programs;
- iv. The Director of the Office of Clinical and Preventive Services;
- v. The Director of the Office of Environmental Health and Engineering;
- vi. The Director of the Office of Public Health Support;
- vii. The Deputy Director of the Office of Quality Health Care; and
- viii. The Director of the Office of Resource Access and Partnerships.

42 CFR 22.2(a) provides that “Director” within the Substance Abuse and Mental Health Services Administration (SAMHSA) shall refer to:

- i. The Director of the Office of Financial Resources;
- ii. The Director of the National Mental Health and Substance Use Policy Lab;
- iii. The Director of the Office of Management, Technology, and Operations;
- iv. The Director of the Center for Mental Health Services;
- v. The Director of the Center for Substance Abuse Prevention;
- vi. The Director of the Center for Substance Abuse Treatment; and
- vii. The Director of the Center for Behavioral Health Statistics and Quality.

The foregoing positions are center, office, division, administration, or bureau directors at the Operating Divisions. These are the highest-ranking career officials at the specified center, office, division, administration or bureau of the Operating Division. By applying this rule to these officials, this final rule will conform practice at the Operating Divisions to the practice imposed by Congress in the 21st Century Cares Act. That is because the foregoing officials are the Operating Divisions equivalents of the NIH Center Directors for whom the 21st Century Cares Act imposed term limits.

It should be noted, though, that at CMS, the Director positions are held by political appointees, who are more easily removable. Therefore, at CMS, this final rule applies to the Deputy Directors, who are career officials who sometimes serve in these positions for many years.

Remaining Provisions of 21 CFR 5.1115(a)

Section 5.1115(a) defines “First Third” to mean the Director of the Center for Drug Evaluation and Research and the Director of the Center for Devices and Radiological Health. Section 5.1115(a) defines “Second Third” to mean the Director of the Center for Food Safety & Applied Nutrition, and the Director of the Center for Tobacco Products. Section 5.1115(a) defines “Third Third” to mean the Director of the Center for Veterinary Medicine and the Director of the Center for Biologics Evaluation and Research.

These definitions, and the reasons for including different Directors in different Thirds, are discussed further below in the discussion of § 5.1115(d).

Remaining Provisions of 42 CFR 22.2(a)

42 CFR 22.2(a) (the equivalent of § 5.1115(a) for Operating Divisions other than FDA) defines “First Third” to mean:

- i. The Director of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (CDC);
- ii. The Center for Surveillance, Epidemiology, and Laboratory Services (CDC);

- iii. The longest-tenured Deputy Director of the Center for Clinical Standards and Quality (CMS);
- iv. The longest-tenured Deputy Director of the Center for Program Integrity (CMS);
- v. The Director of the Office on Trafficking in Persons (ACF);
- vi. The Director of the Center for Policy and Evaluation (ACL);
- vii. The Director of the Center for Financing, Access and Cost Trends (AHRQ);
- viii. The Director of the Center for Evidence and Practice Improvement (AHRQ);
- ix. Director of the Office of Extramural Research, Research, Education, and Priority Populations (AHRQ);
- x. The Director of the Center of Quality Improvement and Patient Safety (AHRQ);
- xi. The Director of the Office Policy, Planning and Partnerships (CDC/ATSDR);
- xii. The Director of the Division of Laboratory Sciences (CDC/ATSDR);
- xiii. The Director of the Office of Health Equity (HRSA);
- xiv. The Associate Administrator of the HIV/AIDS Bureau (HRSA);
- xv. The Associate Administrator of the Healthcare Systems Bureau (HRSA);
- xvi. The Associate Administrator of the Federal Office of Rural Health Policy (HRSA); and
- xvii. The Associate Administrator of the Bureau of Primary Health Care (HRSA).

It defines “Second Third” to mean:

- i. The Director of the National Center for Injury Prevention and Control (CDC);
- ii. The Director of the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (CDC);
- iii. The longest-tenured Deputy Director of the Center for Medicare (CMS);
- iv. The Director of the Office of Human Services Emergency Preparedness Response (ACF);
- v. The Director of the Division of Environmental Health Science and Practice (CDC/ATSDR);
- vi. The Associate Director of the Office of Science (CDC/ATSDR);

- vii. The Director of the Office of Global Health (HRSA);
- viii. The Director of the Office of Civil Rights, Diversity, and Inclusion (HRSA);
- ix. The Associate Administrator of the Maternal and Child Health Bureau (HRSA);
- x. The Associate Administrator of the Bureau of Health Workforce (HRSA);
- xi. The Director of Tribal Self Governance (IHS);
- xii. The Director of Public Health Support (IHS);
- xiii. The Director of Office of Quality (IHS);
- xiv. The Director of the Office of Financial Resources (SAMHSA);
- xv. The Director of the National Mental Health and Substance Use Policy Lab (SAMHSA);
- xvi. The Director of the Office of Management, Technology and Operations (SAMHSA); and
- xvii. The Director of the Center for Mental Health Services (SAMHSA).

It defines “Third Third” to mean:

- i. The Director of the Center for Global Health (CDC);
- ii. The Director of the National Center for Immunization and Respiratory Diseases (CDC);
- iii. The remaining Deputy Director of the Center for Medicare and Medicaid Innovation (CMS);
- iv. The Deputy Administrator of the Center for Innovation and Partnership (ACL);
- v. The Director of the National Institute on Disability, Independent Living and Rehabilitation Research (ACL);
- vi. The Director of the Office of Management and Analytics (CDC/ATSDR);
- vii. The Director of the Office of Planning, Analysis and Evaluation (HRSA);
- viii. The Director of the Office of Women’s Health (HRSA);
- ix. The Associate Administrator of the Office of Federal Assistance Management (HRSA);
- x. The Director of the Office of Direct Service and Contracting Tribes (IHS);
- xi. The Director of the Office of Urban Health Programs (IHS);
- xii. The Director of the Office of Clinical and Preventative Services (IHS);

- xiii. The Director of the Office of Environmental Health and Engineering (IHS);
- xiv. The Director of the Office of Resource Access and Partnerships (IHS);
- xv. The Director of the Center of Substance Abuse Prevention (SAMHSA);
- xvi. The Director of the Center of Substance Abuse Treatment (SAMHSA); and
- xvii. The Director of the Center of Behavioral Health Statistics and Quality (SAMHSA).

21 CFR 5.1115(b) and 42 CFR 22.2(b)

Sections 5.1115(b) and 22.2(b) each provide that, except as otherwise provided in this section, a Director shall be appointed by the Secretary for a term of five years. At the end of the Director's term, the Director may be reappointed by the Secretary for an additional five-year term. There shall be no limit on the number of five-year terms that a Director may serve.

This provision is substantively similar to sections 2033(a)(2)(A) and (a)(2)(B) of the 21st Century Cures Act, which imposed term limits for certain NIH center directors. The Department chose five years as the term length for Directors, in order to conform to the term limits Congress imposed for certain NIH center directors. Under this final rule, as is the case under the 21st Century Cures Act, the Secretary can reappoint each Director at the end of his or her term if the Secretary so chooses. At the same time, the terms limits will open up new avenues for advancement of Department officials. The Department also believes term limits will increase the potential to add diversity of background, experience, and thought to the leadership ranks at the Operating Divisions.

21 CFR 5.1115(c) and 42 CFR 22.2(c)

Sections 5.1115(c) and 22.2(c) each provide that if a Director position becomes vacant before the end of a Director's term, the Director appointed by the Secretary to fill the vacancy shall be appointed for a five-year term starting on the date of such appointment. This provision mirrors section 2033(a)(2)(C) of the 21st Century Cures Act. Section 5.1115(c) makes clear that if there is a vacancy, the new Director who fills the vacancy shall be appointed for a five-year term, rather than until the end of the prior Director's term. The final rule so provides, because the newly-appointed Director should be afforded a five-year term for the same reasons that other Directors are afforded five-year terms.

Sections 5.1115(d) and 22.2(d) each provide that the terms of the current Directors shall expire according to the following schedule:

- 1) The terms of the First Third shall expire on December 13, 2021.
- 2) The terms of the Second Third shall expire on December 13, 2023.
- 3) The terms of the Third Third shall expire on December 15, 2025.

The Department includes this provision to maximize the benefits of term limits while minimizing the disruption they would cause to the Department's ability to carry out its functions. Many current Directors have already served in their positions for more than five years. Under the rationale for this final rule, their terms should expire and they should be reappointed or assigned to a new role. However, the Department believes it would be unduly disruptive to the work of the Department if all these Directors' terms expired at the same time. Accordingly, §§ 5.1115(d) and 22.2(d) each set a schedule for the expiration of the current Directors' terms. Pursuant to §§ 5.1115(d) and 22.2(d), a third of the Directors from each of the Operating Divisions would see their terms expire on December 13, 2021, a third would expire on December 13, 2023, and the terms of the remaining third would expire on December 15, 2025. This would enable the Secretary to have adequate time to determine whether to reappoint all these Directors, and not be unduly disruptive because not all of their terms would expire simultaneously. The Department chose to make the First Third of terms end on December 13, 2021 because this would provide more than sufficient notice and provide the Secretary with ample time to decide whether to reappoint the current Directors who are in the First Third. It also aligns with the end of the NIH Director terms under the 21st Century Cures Act.

As a general matter, under this final rule, the First Third (those whose terms expire on December 13, 2021) includes those Directors at the Operating Divisions who have served the longest. The Second Third includes those who have served the next-longest, and the Third Third includes those Directors who were appointed most recently.

The 21st Century Cures Act provided that then-current NIH center directors were deemed to be appointed for five-year terms as of the date the 21st Century Cures Act was enacted. The Department considered following that approach, but has decided to take a somewhat different approach in this final rule. This is because some Directors have served for many years, and the Department believes it would contravene the rationale for this final rule if all Directors were blanket appointed to five-year terms as of the effective date of this final rule.

21 CFR 5.1115(e) and 42 CFR 22.2(e)

Sections 5.1115(e) and 22.2(e) each provide that nothing in this final rule shall be construed to limit the authority of the most senior leadership to terminate the appointment of a Director before the expiration of such Director's five-year term. This provision is substantively similar to section 2033(a)(2)(E) of the 21 Century Cures Act. The Department includes this provision because it wishes to make clear that this final rule in no way limits the authority of the Secretary or most senior leadership of the Operating Divisions.

21 CFR 5.1115(f) and 42 CFR 22.2(f)

Section 5.1115(f) provides that appointments and reappointments under this section shall be made on the basis of ability and experience as it relates to the mission of the FDA (or, in the case of 42 CFR 22.2(f), the remaining Operating Divisions) and its components, including compliance with any legal requirement that the Secretary determines relevant. This provision is included to conform this final rule to section 2033(a)(2)(F) of the 21 Century Cures Act. The Department includes it for the same reasons that Congress included section 2033(a)(2)(F).

21 CFR 5.1115(g) and 42 CFR 22.2(g)

Section 5.1115(g) provides that if, at the end of a Director's term, the Director is not reappointed to another five-year term, the Director shall be assigned to another position within the FDA (or, in the case of 42 CFR. 22.2(g), the other Operating Divisions) based on the criteria described in paragraph (f). This paragraph makes clear that no officials can be terminated pursuant to this final rule. If the Secretary decides not to reappoint a Director upon the expiration of the Director's term, the Secretary

shall assign the Director to another position in accordance with the criteria described in § 5.1115(f).

Therefore, this final rule does not contravene any civil service protections that might forbid terminating a Director without following procedures specified in the civil service laws.

21 CFR 5.1115(h) and 42 CFR 22.2(h)

Section 5.1115(h) states that unless provided for by statute or regulation, no administrative reorganization of the FDA (or, in the case of 42 CFR 22.2(h)), other Operating Divisions) shall affect the term limits provided for in this section.

Regulatory Impact Analyses

A. Executive Order 12866

This rulemaking is not subject to EO 12866. Under EO 12866 3(d)(3) rules that pertain to agency organization, management, or personnel matters are not subject to the EO, and thus, not subject to a significance determination.

B. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs)

This final rule is not an Executive Order 13771 regulatory action because this final rule is not subject to EO 12866.

C. Regulatory Flexibility Act

Since notice and comment rulemaking is not necessary for this rule, the provisions of the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612) do not apply.

D. Executive Order 13132 (Federalism)

Executive Order 13132 requires agencies to ensure meaningful and timely input by State and local officials in the development of regulatory policies that may have a substantial, direct effect 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. This action has been analyzed in accordance with the principles and criteria contained in Executive Order 13132, and HHS has determined that this action will not have a substantial direct effect or federalism implications on the

States, and would not preempt any State law or regulation or affect the States' abilities to discharge traditional State governmental functions. Therefore, consultation with the States is not necessary.

E. Executive Order 13175

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments." Because this rulemaking does not significantly or uniquely affect the communities of the Indian tribal governments or impose substantial direct compliance costs on them, the funding and consultation requirements of Executive Order 13175 do not apply.

F. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) requires that HHS consider the impact of paperwork and other information collection burdens imposed on the public and, under the provisions of PRA section 3507(d), obtain approval from the Office of Management and Budget (OMB) for each collection of information it conducts, sponsors, or requires through regulations. HHS has determined there are no new information collection requirements associated with this final rule.

G. National Environmental Policy Act

HHS has determined that the rule will not have a significant impact on the environment.

H. Executive Order 12988: Civil Justice Reform

HHS has reviewed this final rule under Executive Order 12988 on Civil Justice Reform and has determined that this rule complies with this Executive Order.

I. Plain Writing Act of 2010

Under the Plain Writing Act of 2010 (Pub. L. 111-274, October 13, 2010), executive departments and agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. The Department has attempted to use plain language in promulgating this proposed rule, consistent with the Federal Plain Writing Act guidelines.

J. Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999, Public Law 105-277, sec. 654, 112 Stat. 2681 (1998) requires Federal departments and agencies to determine whether a policy or regulation could affect family well-being. Section 601 (note) required agencies to assess whether a regulatory action (1) impacted the stability or safety of the family, particularly in terms of marital commitment; (2) impacted the authority of parents in the education, nurturing, and supervision of their children; (3) helped the family perform its functions; (4) affected disposable income or poverty of families and children; (5) was justified if it financially impacted families; (6) was carried out by State or local government or by the family; and (7) established a policy concerning the relationship between the behavior and personal responsibility of youth and the norms of society. HHS has determined that this final rule will not affect family well-being as defined under the statute. This final rule simply provides for terms limits for certain Department officials.

List of Subjects

21 CFR Part 5

Organization and functions (Government agencies).

42 CFR Part 22

Organization and functions (Government agencies).

For the reasons set forth in the preamble, the Department amends 21 CFR part 5 and 42 CFR part 22 as follows:

Title 21 – Food and Drugs

PART 5 — ORGANIZATION

1. The authority citation for part 5 is revised to read as follows:

Authority: 5 U.S.C. 301; 5 U.S.C. 552.

2. Add § 5.1115 to read as follows:

§ 5.1115 Term limits for Center Directors.

(a) *Definitions.* For purposes of this section:

(1) *Director* shall refer to the Food and Drug Administration (FDA) officials holding the following positions:

- (i) The Director of the Center for Biologics Evaluation and Research;
- (ii) The Director of the Center for Devices and Radiological Health;
- (iii) The Director of the Center for Drug Evaluation and Research;
- (iv) The Director of the Center for Food Safety and Applied Nutrition;
- (v) The Director of the Center for Tobacco Products;
- (vi) The Director of the Center for Veterinary Medicine; and
- (vii) The Director of the Oncology Center of Excellence.

(2) *First Third* shall refer to the Director of the Center for Drug Evaluation and Research and the Director of the Center for Devices and Radiological Health.

(3) *Second Third* shall refer to the Director of the Center for Food Safety & Applied Nutrition and the Director of the Center for Tobacco Products.

(4) *Third Third* shall refer to the Director of the Center for Veterinary Medicine and the Director of the Center for Biologics Evaluation and Research.

(b) *Term limits.* Except as otherwise provided in this section, a Director shall be appointed by the Secretary for a term of five years. At the end of the Director's term, the Director may be reappointed by the Secretary for an additional five-year term. There shall be no limit on the number of five-year terms that a Director may serve.

(c) *Vacancies.* If a Director position becomes vacant before the end of a Director's term, the Director appointed by the Secretary to fill the vacancy shall be appointed for a five-year term starting on the date of such appointment.

(d) *Current Directors.* The terms of the current Directors shall expire according to the following schedule:

- (1) The terms of the First Third shall expire on December 13, 2021.

(2) The terms of the Second Third shall expire on December 13, 2023.

(3) The terms of the Third Third shall expire on December 15, 2025.

(e) *Rule of construction.* Nothing in this section shall be construed to limit the authority of the Secretary or the Commissioner of Food and Drugs to terminate the appointment of a Director before the expiration of such Director's five-year term.

(f) *Nature of appointment.* Appointments and reappointments under this section shall be made on the basis of ability and experience as it relates to the mission of the Food and Drug Administration and its components, including compliance with any legal requirement that the Secretary determines relevant.

(g) *Reassignment at end of term.* If, at the end of a Director's term, the Director is not reappointed to another five-year term, the Director shall be assigned to another position within the Food and Drug Administration based on the criteria described in paragraph (f) of this section.

(h) *Effect of reorganization.* Unless provided for by statute or regulation, no administrative reorganization of the Food and Drug Administration shall affect the term limits provided for in this section.

Title 42 – Public Health

PART 22—PERSONNEL OTHER THAN COMMISSIONED OFFICERS

3. The authority citation for part 22 is revised to read as follows:

Authority: 5 U.S.C. 301; 5 U.S.C. 552.

4. Add § 22.2 to read as follows:

§ 22.2 Term limits for Center, Office, Administration, or Bureau Directors.

(a) *Definitions.* For purposes of this section:

(1) *Director* shall refer to:

(i) At the Administration for Children and Families (ACF):

(A) The Director of the Office of Human Services Emergency Preparedness and Response; and

(B) The Director of Office on Trafficking in Persons.

(ii) At the Administration for Community Living (ACL):

(A) The Deputy Administrator of the Center for Innovation and Partnership;

(B) The Director of the Center for Policy and Evaluation; and

(C) The Director of the National Institute on Disability, Independent Living, and Rehabilitation Research.

(iii) At the Agency for Healthcare Research and Quality (AHRQ):

(A) The Director of the Center for Financing, Access and Cost Trends;

(B) The Director of the Center for Evidence and Practice Improvement;

(C) The Director of the Office of Extramural Research, Research, Education, and Priority Populations; and

(D) The Director of the Center of Quality Improvement and Patient Safety.

(iv) At the Centers for Disease Control and Prevention (CDC):

(A) The Director of the Center for Global Health;

(B) The Director of the Center for Preparedness and Response;

(C) The Director of the Center for State, Tribal, Local, and Territorial Support;

(D) The Director of the Center for Surveillance, Epidemiology, and Laboratory Services;

(E) The Director of the National Center for Health Statistics;

(F) The Director of the National Center on Birth Defects and Developmental Disabilities;

(G) The Director of the National Center for Chronic Disease Prevention and Health Promotion;

(H) The Director of the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry;

(I) The Director of the National Center for Injury Prevention and Control;

(J) The Director of the National Center for Immunization and Respiratory Diseases;

(K) The Director of the National Center for Emerging and Zoonotic Infectious Diseases;

(L) The Director of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention;

(M) The Director of the Agency for Toxic Substances and Disease Registry (ATSDR) Office of Management and Analytics;

(N) The Director of the ATSDR Division of Environmental Health Science and Practice;

(O) The Director of the ATSDR Office of Policy, Planning, and Partnerships;

(P) The Associate Director of the ATSDR Office of Science; and

(Q) The Director of the ATSDR Division of Laboratory Sciences.

(v) At the Centers for Medicare & Medicaid Services (CMS):

(A) The Deputy Directors of the Center for Clinical Standards and Quality;

(B) The Deputy Directors of the Center for Medicare and Medicaid Innovation;

(C) The Deputy Directors of the Center for Medicare;

(D) The Deputy Directors of the Center for Medicaid and CHIP Services;

(E) The Deputy Directors of the Center for Program Integrity; and

(F) The Deputy Directors of the Center for Consumer Information and Insurance Oversight.

(vi) At the Health Resources and Services Administration (HRSA):

(A) The Director of the Office of Global Health;

(B) The Director of the Office of Health Equity;

- (C) The Director of the Office of Planning, Analysis and Evaluation;
- (D) The Director of the Office of Civil Rights, Diversity, and Inclusion;
- (E) The Director of the Office of Women's Health;
- (F) The Associate Administrator of the Maternal and Child Health Bureau;
- (G) The Associate Administrator of the HIV/AIDS Bureau;
- (H) The Associate Administrator of the Healthcare Systems Bureau;
- (I) The Associate Administrator of the Federal Office of Rural Health Policy;
- (J) The Associate Administrator of the Bureau of Primary Health Care;
- (K) The Associate Administrator of the Bureau of Health Workforce; and
- (L) The Associate Administrator of the Office of Federal Assistance Management.

(vii) At Indian Health Service (IHS):

- (A) The Director of the Office of Direct Service and Contracting Tribes;
- (B) The Director of the Office of Tribal Self Governance;
- (C) The Director of the Office of Urban Indian Health Programs;
- (D) The Director of the Office of Clinical and Preventive Services;
- (E) The Director of the Office of Environmental Health and Engineering;
- (F) The Director of the Office of Public Health Support;
- (G) The Deputy Director of the Office of Quality Health Care; and
- (H) The Director of the Office of Resource Access and Partnerships.

(viii) At the Substance Abuse and Mental Health Services Administration (SAMHSA):

- (A) The Director of the Office of Financial Resources;
- (B) The Director of the National Mental Health and Substance Use Policy Lab;
- (C) The Director of the Office of Management, Technology, and Operations;
- (D) The Director of the Center for Mental Health Services;
- (E) The Director of the Center for Substance Abuse Prevention;
- (F) The Director of the Center for Substance Abuse Treatment; and
- (G) The Director of the Center for Behavioral Health Statistics and Quality.

(2) *First Third* shall mean:

- (i) The Director of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (CDC);
- (ii) The Center for Surveillance, Epidemiology, and Laboratory Services (CDC);
- (iii) The longest-tenured Deputy Director of the Center for Clinical Standards and Quality (CMS);
- (iv) The longest-tenured Deputy Director of the Center for Program Integrity (CMS);
- (v) The Director of the Office on Trafficking in Persons (ACF);
- (vi) The Director of the Center for Policy and Evaluations (ACL);
- (vii) The Director of the Center for Financing, Access and Cost Trends (AHRQ);
- (viii) The Director of the Center for Evidence and Practice Improvement (AHRQ);
- (ix) The Director of the Office of Extramural Research, Research, Education, and Priority Populations (AHRQ);
- (x) The Director of the Center of Quality Improvement and Patient Safety (AHRQ);
- (xi) The Director of the Office Policy, Planning and Partnerships (CDC/ATSDR);
- (xii) The Director of the Division of Laboratory Sciences (CDC/ATSDR);
- (xiii) The Director of the Office of Health Equity (HRSA);

- (xiv) The Associate Administrator of the HIV/AIDS Bureau (HRSA);
- (xv) The Associate Administrator of the Healthcare Systems Bureau (HRSA);
- (xvi) The Associate Administrator of the Federal Office of Rural Health Policy (HRSA); and
- (xvii) The Associate Administrator of the Bureau of Primary Health Care (HRSA).

(3) *Second Third* shall mean:

- (i) The Director of the National Center for Injury Prevention and Control (CDC);
- (ii) The Director of the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (CDC);
- (iii) The longest-tenured Deputy Director of the Center for Medicare (CMS);
- (iv) The Director of the Office of Human Services Emergency Preparedness Response (ACF);
- (v) The Director of the Division of Environmental Health Science and Practice (CDC/ATSDR);
- (vi) The Associate Director of the Office of Science (CDC/ATSDR);
- (vii) The Director of the Office of Global Health (HRSA);
- (viii) The Director of the Office of Civil Rights, Diversity, and Inclusion (HRSA);
- (ix) The Associate Administrator of the Maternal and Child Health Bureau (HRSA);
- (x) The Associate Administrator of the Bureau of Health Workforce (HRSA);
- (xi) The Director of Tribal Self Governance (IHS);
- (xii) The Director of Public Health Support (IHS);
- (xiii) The Director of Office of Quality (IHS);
- (xiv) The Director of the Office of Financial Resources (SAMHSA);
- (xv) The Director of the National Mental Health and Substance Use Policy Lab (SAMHSA);

- (xvi) The Director of the Office of Management, Technology and Operations (SAMHSA); and
- (xvii) The Director of the Center for Mental Health Services (SAMHSA).

(4) *Third Third* shall mean:

- (i) The Director of the Center for Global Health (CDC);
- (ii) The Director of the National Center for Immunization and Respiratory Diseases (CDC);
- (iii) The remaining Deputy Director of the Center for Medicare and Medicaid Innovation (CMS);
- (iv) The Deputy Administrator of the Center for Innovation and Partnership (ACL);
- (v) The Director of the National Institute on Disability, Independent Living and Rehabilitation Research (ACL);
- (vi) The Director of the Office of Management and Analytics (CDC/ATSDR);
- (vii) The Director of the Office of Planning, Analysis and Evaluation (HRSA);
- (viii) The Director of the Office of Women's Health (HRSA);
- (ix) The Associate Administrator of the Office of Federal Assistance Management (HRSA);
- (x) The Director of the Office of Direct Service and Contracting Tribes (IHS);
- (xi) The Director of the Office of Urban Health Programs (IHS);
- (xii) The Director of the Office of Clinical and Preventative Services (IHS);
- (xiii) The Director of the Office of Environmental Health and Engineering (IHS);
- (xiv) The Director of the Office of Resource Access and Partnerships (IHS);
- (xv) The Director of the Center of Substance Abuse Prevention (SAMHSA);
- (xvi) The Director of the Center of Substance Abuse Treatment (SAMHSA); and

(xvii) The Director of the Center of Behavioral Health Statistics and Quality (SAMHSA).

(b) *Term limits.* Except as otherwise provided in this section, a Director shall be appointed by the Secretary for a term of five years. At the end of the term of a Director, the Director may be reappointed by the Secretary for an additional five-year term. There shall be no limit on the number of five-year terms that a Director may serve.

(c) *Vacancies.* If a Director position becomes vacant before the end of a Director's term, the Director appointed by the Secretary to fill the vacancy shall be appointed for a five-year term starting on the date of such appointment.

(d) *Current Directors.* The terms of the current Directors shall expire according to the following schedule.

(1) The terms of the First Third shall expire on December 13, 2021.

(2) The terms of the Second Third shall expire on December 13, 2023.

(3) The terms of the Third Third shall expire on December 15, 2025.

(e) *Rule of construction.* Nothing in this section shall be construed to limit the authority of the Secretary, or the most senior leadership of ACF, ACL, AHRQ, CDC, CMS, HRSA, IHS, or SAMHSA to terminate the appointment of a Director before the expiration of such Director's five-year term.

(f) *Nature of appointment.* Appointments and reappointments under this section shall be made on the basis of ability and experience as it relates to the mission of the ACF, ACL, AHRQ, CDC, CMS, HRSA, IHS, and SAMHSA.

(g) *Reassignment at end of term.* If, at the end of a Director's term, the Director is not reappointed to another five-year term, the Director shall be assigned to another position within ACF, ACL, AHRQ, CDC, CMS, HRSA, IHS, or SAMHSA based on the criteria described in paragraph (f) of this section.

(h) *Effect of reorganization.* Unless provided for by statute or regulation, no administrative reorganization of ACF, ACL, AHRQ, CDC, CMS, HRSA, IHS, or SAMHSA shall affect the term limits provided for in this section.

Date: January 11, 2021.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.