



## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

### 14 CFR Part 1241

[Document Number NASA-20-091; Docket Number-NASA-2020-0001]

RIN 2700-AE51

### To Research, Evaluate, Assess, and Treat (TREAT) Astronauts

**AGENCY:** National Aeronautics and Space Administration (NASA).

**ACTION:** Final rule.

**SUMMARY:** The National Aeronautics and Space Administration (NASA) is adopting, without change, an interim rule that implements the provisions of the TREAT Astronauts Act to provide for the medical monitoring and diagnosis of conditions that are potentially spaceflight-associated and treatment of conditions that are spaceflight-associated for former U.S. Government astronauts and payload specialists.

**DATES:** *Effective:* [INSERT DATE PUBLISHED IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Gwyn E. Smith, Manager, Policy Development and Integration, Office of the Chief Health and Medical Officer, 202.358.0584.

### SUPPLEMENTARY INFORMATION:

#### I. Background

NASA published an interim rule in the Federal Register at 85 FR 15352 on March 18, 2020, that implements the provisions of the TREAT Astronauts Act. The rule provides for the medical monitoring and diagnosis of conditions that are potentially spaceflight-associated and treatment of conditions that are spaceflight-associated for former U.S. Government astronauts and payload specialists. NASA is adopting this interim rule as a final rule without change.

#### II. Public Comment Discussion

NASA issued interim final rule, “To Research, Evaluate, Assess, and Treat (TREAT) Astronauts,” which was published in the Federal Register on March 18, 2020 (85 FR 15352).

The public comment period on the interim final rule closed on May 18, 2020, and NASA received six comments from two former astronauts, three individuals interested in former astronaut health care, and an individual from Taiwan who asked a question about Formosan astronauts, not related to this rule. No significant issues or questions were raised by the commenters and no changes were made to the rule. Relevant questions and comments presented are addressed in routine communications with the former astronauts. NASA would like to thank all commenters for their thoughtful responses.

One commenter recommended rewording the definition of “spaceflight associated condition” to make it more understandable, specifically asking what the phrase “determines is at least as likely as not to have resulted from participation in spaceflight-related activities” meant. NASA, when making determinations on the association between health outcomes and occupational exposures related to spaceflight, relies on available evidence, including an individual’s clinical history, epidemiological assessments, and data from human research, as well as expert medical opinion. Because direct causation is very difficult to establish in many cases, a determination of presumptive association between spaceflight and a health outcome requires that the evidence and expert medical opinion together suggest that the spaceflight exposures received by an individual are as likely to cause the health outcome, as to not cause the health outcome. The focus of NASA’s inquiry is whether spaceflight exposures contributed to the health condition, not all other possible exposures. Using “at least as likely as not” as the criterion for decision making lowers the threshold for determining an association between spaceflight exposures and health outcomes, accounting for possible uncertainties involved in making such a determination. NASA chose this approach based on the processes used by other Federal agencies who must make similar determinations when direct causation cannot otherwise be established.

Another commenter had several questions about specifically how NASA would implement this rule, asking how a former astronaut would know what conditions would be considered related to spaceflight and if the NASA Flight Medicine Clinic would be an advocate

on their behalf. NASA is developing internal policy and procedures for NASA employees necessary to implement this rule. In addition, NASA will continue to communicate with former astronauts through multiple media, including the annual astronaut reunion, newsletters, online via the Life Sciences Data Archive, and NASA TREAT Astronauts Act Web sites, as well as personal communications with former astronauts.

Several commenters offered supporting thoughts such as, "...the TREAT Astronauts Act as nothing but a resourceful and helpful program..." and "To gain more support to pass this rule, I recommend ensuring more scientists and doctors will be hired at NASA to observe former astronauts and payload specialists, so that this effort does not take away from other important NASA programs" and asked how this Act would increase former astronaut participation and to elaborate on the differences between the Lifetime Surveillance of Astronaut Health (LSAH) program and TREAT Astronauts Act. NASA appreciates the support for this rule and provides detailed information to former astronauts on the specifics of the implementation of this rule. NASA anticipates increased participation from former astronauts, based on discussions with them as to the benefits of the program and to future astronauts. The LSAH program provides lifetime monitoring for former astronauts while the TREAT Astronauts Act provides funding for treatment of spaceflight associated conditions. More details can be found at <https://www.nasa.gov/hhp/treat-act>.

### **III. Regulatory Analysis Section**

#### **Executive Order 12866 - Regulatory Planning and Review and Executive Order 13563 – Improving Regulation and Regulatory Review**

Executive Orders (EO) 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). EO 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

This rule is not a significant regulatory action and has not been reviewed by the Office of Management and Budget in accordance with EO 12866.

**Executive Order 13771 – Reducing Regulations and Controlling Regulatory Costs**

This rule is not an EO 13771 regulatory action because final rule is not significant under EO 12866.

**Regulatory Flexibility Act**

It has been certified that this rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not have a significant economic impact on a substantial number of small entities.

**Paperwork Reduction Act**

This rule contains information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements are found under Office of Management and Budget control number 2700-0171, NASA TREAT Astronauts Act.

**Unfunded Mandates Reform Act of 1995**

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate or by the private sector, of \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments.

**List of Subjects in 14 CFR Part 1241**

Astronaut, Health, Medical.

**Interim Rule Adopted as Final Without Change**

**PART 1241—TO RESEARCH, EVALUATE, ASSESS, AND TREAT (TREAT)**

**ASTRONAUTS**

Accordingly, the interim rule adding 14 CFR part 1241 which was published at 85 FR 15352 on March 18, 2020, is adopted as final without change.

Nanette Smith,

Team Lead, NASA Directives and Regulations.

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