



**NATIONAL AERONAUTICS AND SPACE ADMINISTRATION**

**14 CFR Part 1241**

**[Document Number NASA-20-028: Docket Number-NASA-2020-0001]**

**RIN 2700-AE51**

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

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

**ACTION:** Interim final rule; request for comments.

**SUMMARY:** With this interim final rule, the National Aeronautics and Space Administration (NASA) is amending its regulations to add a new part that will implement the provisions of the TREAT Astronauts Act. The new regulations will 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 OF PUBLICATION IN THE FEDERAL REGISTER].

*Comments due:* Send comments on or before [INSERT 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** You may send comments, identified by docket number NASA-2019-0004 and/or RIN number 2700-AE51, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for sending comments.
- E-mail: [HQ-TREATAstronautsAct@nasa.gov](mailto:HQ-TREATAstronautsAct@nasa.gov). Include docket number NASA-2019-0004 and/or RIN number 2700-AE51 in the subject line of the message.

• Mail: NASA Headquarters, Mail Code 2M21, ATTN: Gwyn E. Smith, 300 E St SW, Washington, DC 20546-0001.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Gwyn E. Smith, Policy Manager, Office of the Chief Health and Medical Officer, 1-833-996-1685, HQ-TREATAstronautsAct@nasa.gov

**SUPPLEMENTARY INFORMATION:**

**I. Background**

NASA currently has a voluntary medical monitoring program, Lifetime Surveillance of Astronaut Health (LSAH) program, for all U.S. Government astronauts and payload specialists at the NASA Johnson Space Center (JSC). Once they leave the astronaut corps, former U.S. Government astronauts and payload specialists rely on workers' compensation and other U.S. Government programs to provide diagnosis and treatment for spaceflight-associated conditions. There is no formal mechanism for NASA to receive diagnosis and treatment data on such conditions.

As of November 2019, there are approximately 250 living former U.S. Government astronauts and payload specialists. The Agency currently affords occupationally related medical monitoring services through the LSAH program to former U.S. Government astronauts and payload specialists at the JSC with a 60–70 percent participation rate.

On March 21, 2017, the President signed into law the National Aeronautics and Space Administration Transition Authorization Act of 2017, Pub. L. No. 115-10 (2017). Title IV, Subtitle D, the “To Research, Evaluate, Assess, and Treat Astronauts Act” (hereafter “TREAT Astronauts Act” or “Act”) is codified at Section 20149 of Title 51 of the U.S. Code.

The TREAT Astronauts Act provides NASA the authority to expand the voluntary monitoring program by developing a more comprehensive occupational surveillance program that will enable earlier detection and diagnosis of medical conditions “potentially associated” with spaceflight and treatment of medical conditions associated with spaceflight. NASA currently uses data from the LSAH program to tailor clinical care for individual astronauts, as well as to inform the human systems risks, current spaceflight operations, and future vehicle standards. The comprehensive occupational surveillance program will provide NASA with more comprehensive data that will ultimately contribute to an improved understanding of the long-term impact of spaceflight. This enhanced program is expected to increase the former U.S. Government astronaut and payload specialist participation rate in the occupational surveillance program to over 80 percent.

Human spaceflight poses significant challenges and is full of substantial risk. NASA and its astronauts acknowledge and accept the risks of spaceflight are beyond those of ordinary daily living. Participation in long duration missions or multiple shorter duration missions, increases health risks such as, vision impairment, bone demineralization, and behavioral health issues. In addition, exposure to high levels of radiation and microgravity can result in acute and long-term health consequences that can increase the risk of cancer and tissue degeneration and have potential effects on the musculoskeletal system, central nervous system, cardiovascular system, immune function, and vision.

NASA has also seen an increase in health issues former U.S. Government astronauts and payload specialists face, many years after their NASA service. One of the vital tools NASA needs to prepare for future long-duration and exploration missions is more data on the health effects humans face in spaceflight. Data collected under the TREAT Astronauts Act will allow NASA to examine health trends in astronauts over the course of their lifetime to understand better the physical, behavioral, microbiological, and molecular reaction of the human body. These data will also contribute to the overall knowledge of the Agency and serve to identify spaceflight risks to human health and develop mitigation strategies as NASA moves ahead to long-duration and exploration missions. Given the fact that there are so few astronauts and such limited data, increased participation to get more data is critical. NASA is learning daily of the untoward effects of human spaceflight on the human body. In order to prepare for the Moon in 2024, NASA needs to understand these effects so appropriate mitigation measures can be taken now.

This program will inform future generations by providing health data showing the effects of spaceflight activities on active and former U.S. Government astronauts and payload specialists and thereby ensuring that their legacy and NASA's mission continues. This data will become increasingly valuable to improving our understanding of many diseases humans face on Earth.

## **II. Section-by-section analysis**

### **Section 1241.10 Covered medical care**

This section establishes key tenets of the program as defined in the TREAT Astronauts Act unless specifically stated otherwise. NASA will provide monitoring and diagnosis for conditions potentially associated with spaceflight and treatment for conditions associated with spaceflight. For clarity and ease of reading, we are using "spaceflight-associated condition" as

defined in 14 CFR 1241.15 versus “condition associated with spaceflight” as used in the TREAT Astronauts Act. Monitoring, diagnosis, and treatment will be provided by a local health care provider if it is inadvisable for the former U.S. Government astronaut or payload specialist to travel to the JSC. A provision has been added to also allow for monitoring, diagnosis, and treatment at a local health care provider if it is advantageous to the Government. For example, if additional tests are needed after the individual has returned home from JSC, they could be done locally if it is more cost effective. NASA will provide medical monitoring, diagnosis, and treatment without a cost sharing obligation imposed on the former U.S. Government astronaut or payload specialist. This means NASA will pay, as a secondary payer, for any medical costs associated with the monitoring and diagnosis of a condition that is potentially associated with spaceflight and will pay, as the secondary payer, for any medical costs associated with the treatment of a condition that is associated with spaceflight. This includes deductibles, coinsurance, copayments, and similar charges, but excludes insurance premiums. Lastly, the law limits NASA’s authority to pay for medical treatment to the role of secondary payer. The type of primary coverage available to former U.S. Government astronauts and payload specialists will depend on their status at the time of their active astronaut career and any current health plan, Federal benefits program, or other workers’ compensation coverage that may apply. For former U.S. Government astronauts and payload specialists who believe they have a condition related to their spaceflight, they must first seek treatment from the Department of Defense Military Health System, the Department of Labor Office of Workers’ Compensation Programs Division of Federal Employees’ Compensation, or through their private health insurance, where applicable. The JSC Flight Medicine Clinic will assist the former U.S. Government astronauts and payload specialists with these processes as well as filing a claim with NASA.

## **Section 1241.15 Definitions**

This section defines terms used in the TREAT Astronauts Act and this rule. We define:

- “Conditional payments” as described in the TREAT Astronauts Act. This helps ensure the U.S. Government astronauts and payload specialists get prompt monitoring, diagnosis, and treatment for potential spaceflight-associated conditions, prior to primary payer formal claim submission and adjudication, as appropriate.

- “Cost sharing” as described in the TREAT Astronauts Act prescribes that former U.S. Government astronauts and payload specialists participating in the program will receive monitoring, diagnosis, and treatment without cost sharing obligation. This means that medical monitoring, diagnosis, or treatment authorized under this Act shall be provided without any deductible, copayment, or other cost sharing obligation.

- “Monitoring, diagnosis, and treatment” as consistent with current use in the medical community. Diagnosis and treatment are provided, consistent with the accepted standard of care. However, due to the unique nature of spaceflight, monitoring is based on a NASA astronaut spaceflight exposure clinical assessment. For example, as part of routine monitoring, NASA provides bone density scanning for young healthy males. This testing is beyond the accepted standard of care.

- “Eligible individual” to include both former U.S. Government astronauts and former payload specialists who have flown in space, while specifically excluding others who are not included in these groups. U.S. Government astronaut is defined in the TREAT Astronauts Act as the meaning given the term “Government astronaut” in 51 U.S.C 50902, except it does not include an individual who is an international partner astronaut. The term “Government astronaut” is defined in 51 U.S.C. 50902.

For clarification, the following are specifically excluded:

- (1) Astronauts of other United States Government agencies – only astronauts who participate in NASA programs are eligible under the TREAT Astronauts Act, so if Department of Defense or Department of Labor, for example, had astronauts, they would not be covered under the TREAT Astronauts Act;
- (2) Employees of commercial spaceflight companies who were never employed by NASA nor a member of the Uniformed Services assigned to NASA – commercial spaceflight astronauts, i.e., astronauts who flew for commercial spaceflight companies, even if they participated in a mission to a NASA vehicle, say the International Space Station, are not eligible under the TREAT Astronauts Act;
- (3) International partner astronauts – a term used specifically for NASA’s partners in the International Space Station, excluding Russia, are specifically excluded in the TREAT Astronauts Act;
- (4) Employees of foreign governments – astronauts who have flown to space with NASA but are not U.S. Government astronauts are not eligible; and
- (5) Private individuals or tourists who have flown in space – private individuals and tourists who have flown to space with NASA, but are not U.S. Government astronauts are not eligible; and
- (6) Former astronauts, including members of the Uniformed Services, and former payload specialists who have not flown in space – The definition of U.S. Government astronauts includes only those individuals who have flown into space, and therefore, those who have not flown to space are not eligible under the TREAT Astronauts Act.

We use the term “eligible individual” in this rule instead of the compound term “former U.S. Government astronaut and former payload specialists” as used in the TREAT Astronauts Act to clarify specifically who may participate in this program.

- “Program” to mean the medical monitoring, diagnosis, and treatment authorized by the TREAT Astronauts Act to enhance the readability of the rule.

- “Primary Payer” as it is commonly used within the medical community. Primary payer means the entity that pays first, up to the limits of its coverage.

- “Secondary Payer” to mean the entity that pays after all primary payers have paid, up to the limits of their coverage. This means NASA will pay, in toto, as the secondary payer for any monitoring and diagnosis for potentially spaceflight-associated conditions and for any treatment for spaceflight-associated conditions. This includes any out-of-pocket cost-sharing expenses not covered by the primary payers.

- “Spaceflight-Associated Condition” to mean the same as the TREAT Astronauts Act “condition associated with spaceflight.” This change in terminology enhances readability of the rule.

- “TREAT Astronauts Act Board (TAAB)” as the internal NASA board that makes recommendations to the NASA Administrator or designee. The internal NASA charter for this board will detail the functions, membership, and operations. The decision-making process is detailed in 14 CFR 1241.6.

### **Section 1241.20 Eligibility**

This section addresses eligibility of the former U.S. Government astronauts and payload specialists. There are currently approximately 250 former U.S. Government astronauts and payload specialists who may participate in this program. Eligible individuals must also meet

other requirements defined herein to receive monitoring, diagnosis, and treatment under this program. Participation is strictly voluntary, that is, NASA cannot require former U.S. Government astronaut and payload specialists to participate.

### **Section 1241.25 Basic program**

This section describes the basic components of the program offered to former U.S. Government astronauts and payload specialists. In addition to providing monitoring, diagnosis, and treatment, NASA, as part of the no cost sharing obligation, will also cover travel expenses incurred. NASA currently covers travel expenses for its occupational surveillance program and will extend this no cost sharing across the program. Monitoring of potentially spaceflight-associated conditions is nominally provided at the JSC Flight Medicine Clinic. When necessary, due to the health of the former U.S. Government astronaut or payload specialist, monitoring may be provided locally, so as not to burden the eligible individual with travel. In addition, NASA may also opt to use a provider local to the eligible individual, if it is otherwise advantageous to the Government. This allows NASA to reduce costs as much as possible. Diagnosis and treatment is handled on a case-by-case basis, with the location of the provider dependent on the medical appropriateness of the facility, patient, preferences, cost effectiveness, and other pertinent factors. Each case is different and this allows NASA to provide the best possible care for each eligible individual. Eligible individuals who agree to participate in this program must agree that NASA is entitled to copies of any medical records associated with the monitoring, diagnosis, and treatment. They must further agree to submit all paperwork necessary for NASA to obtain copies of these records. And finally, they must agree that NASA may use and disclose this data within the limits of the law.

NASA will provide monitoring and diagnosis of eligible individuals for conditions potentially associated with spaceflight and treatment for spaceflight-associated conditions. NASA provides a lifetime occupation surveillance program, which includes a standard set of monitoring offered yearly to former U.S. Government astronauts and payload specialists. In addition to this yearly offering, additional monitoring is provided, as necessary, based on each eligible individual's medical needs. A provision has been added specifically for NASA to also request autopsies, as part of monitoring, be performed as they may contribute substantially to the knowledge of spaceflight physiology or pathology.

As mentioned previously, NASA is not authorized to provide monitoring and diagnosis for conditions not potentially associated with spaceflight or treatment for conditions not spaceflight-associated. Should a condition be diagnosed that is not related to spaceflight, the individual will be referred to their primary care physician.

### **Section 1241.30 Program participation and claims submission**

This section details the steps an eligible individual must take, with assistance from the JSC Flight Medicine Clinic, to participate in this program. Former U.S. Government astronauts and payload specialists already receive an annual invitation from NASA to participate in NASA's occupational surveillance program. No claim is required to participate in NASA's occupational surveillance program. This current program has a 60-70 percent participation rate. Eligible individuals must first seek primary coverage before submitting a claim to NASA, as NASA is a secondary payer. The type of primary coverage available to former U.S. Government astronauts and payload specialists will depend on their status at the time of their active astronaut career and any current health plan, Federal benefits program, or other workers' compensation coverage that may apply. For former U.S. Government astronauts and payload specialists who

believe they have a condition related to their spaceflight, they must first seek treatment from the Department of Defense Military Health System, the Department of Labor Office of Workers' Compensation Programs Division of Federal Employees' Compensation, or through their private health insurance, where applicable. If the eligible individual is enrolled, or eligible to be enrolled in the U.S. Department of Veterans Affairs (VA) health care system and chooses to obtain care and services through VA, the individual will receive health care benefits in accordance with chapter 17 of title 38, United States Code, as implemented by the Secretary of Veterans Affairs. Moreover, as to the costs of VA care and services, there will be no "coordination of benefits," as this term is generally understood in the health care industry, between VA and NASA. That is, VA would pay the full cost of the care. Under the TREAT Astronauts program, the eligible individual may seek reimbursement from NASA for any out-of-pocket copayment(s) he or she paid to VA for care of a condition that NASA determines is associated with spaceflight; and finally, VA has no special treatment authority (or copayment exemption) for former U.S. Government astronauts and payload specialists seeking treatment for conditions associated with spaceflight. As to compensation for disability related to service in the Armed Forces, an eligible individual who has Veteran status is free to file a claim for disability compensation with the Veterans Benefits Administration, pursuant to 38 CFR part 3. The JSC Flight Medicine Clinic will assist the former U.S. Government astronauts and payload specialists with these processes as well as filing a claim with NASA.

This section also details the specific information required to submit a claim to NASA and identifies a Web site where additional information is available. The NASA Flight Medical Clinic will assist eligible individuals with claims submission, but is not authorized to prepare the claim on behalf of the eligible individual.

### **Section 1241.35 Claims review and decision**

This section explains the review and decision-making process for claims submitted to NASA by eligible individuals. The TREAT Astronauts Act Board (TAAB) is an internal NASA board of physicians who will review claims submitted to NASA. The TAAB will consider all information, including information about other exposures, provided for a case and consult with other experts and specialists as appropriate. The TAAB will provide a recommendation to the Administrator or designee who will make the final decision on approval or denial of the claim. The eligible individual will be notified of the decision promptly and, should the claim be denied, be afforded the opportunity to submit additional information for reconsideration of the claim. There is no limit to the number of times an eligible individual can submit new information through a reconsideration request.

### **Section 1241.40 Payment of approved claims**

This section details the payment process for approved claims. NASA payments are applied secondarily to other U.S. Government entities or primary payers and may include the remaining out-of-pocket costs from primary payer coverage. Travel expenses are paid consistent with the Federal Travel Regulations and may include expenses for an assistant should the eligible individual need travel assistance. Conditional payments are also allowed to ensure the eligible individual gets the care needed promptly. NASA may attempt to recover these costs from the primary payer or the eligible individual if the claim is subsequently denied.

### **Section 1241.45 Collaboration with other agencies**

This section simply states that NASA will collaborate with other agencies as necessary to acquire medical records as allowable by law. As a condition of participating in the program, eligible individuals will have consented to allowing NASA to collect this information.

## **Section 1241.50 Records, confidentially, privacy and data use**

This section states that NASA will adhere to all required privacy regulations and policies and will enter into data sharing agreements with other agencies as necessary to obtain required data.

### **III. Effect of Rulemaking**

Title 14 of the Code of Federal Regulations, as revised by this interim final rulemaking, represents NASA's implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent NASA guidance must be read to conform with this rulemaking, if possible, or if not possible, such guidance is superseded by this rulemaking.

### **IV. Regulatory Analysis Section**

#### **Administrative Procedure Act (APA)**

The Administrative Procedure Act requires notice of any proposed rule to be published in the Federal Register "unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with the law," 5 U.S.C. 553(b). NASA has determined that through its extensive outreach efforts that actual notice has been provided to all interested parties—250 former astronauts and payload specialists, including several current Federal employees, and that this rule has no effect on the public beyond the 250 former astronauts. In drafting these regulations, NASA officials met with former U.S. Government astronauts and payload specialists, communicating and soliciting input from as many individuals as possible, through a variety of venues, including communications from the former NASA Administrator, professional meetings, the Potomac Institute for Policy Studies, 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 on how best to implement the program. These mechanisms have allowed us to notify the small group of interested individuals and enabled them opportunities to provide NASA with input regarding the development of this program. While an Internet posting and a single meeting has been found insufficient to replace publication in the Federal Register, *see Utility Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 754 (D.C. Cir. 2001), NASA's efforts to provide actual notice was much more expansive and successful. *See Common Carrier Conference-Irregular Route v. United States*, 534 F.2d 981, 982 (D.C. Cir. 1976) (finding notice adequate because the affected parties were "generally on notice" through conduct of agency). Based on the forgoing, the agency has concluded that the individuals affected by this regulation have received actual notice and that publication in the Federal Register is not necessary. Nevertheless, for the avoidance of potential controversy and because of potential public interest, NASA has decided to publish these regulations as an interim final rule in the Federal Register.

In accordance with 5 U.S.C. 553, the Administrator of NASA has also concluded that there is good cause to publish this rule without prior opportunity for public comment. Good cause may be shown when the Agency finds that "notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." *See* 5 U.S.C. 553(b)(B). Furthermore, in accordance with 5 U.S.C. § 553, the Administrator of NASA has concluded there is good cause to publish this rule with an immediate effective date. An agency may dispense with the required 30 day effective date if "as otherwise provided by the agency for good cause found and published with the rule." *See* 5 U.S.C. 553(d)(3).

As explained above, on March 21, 2017, the President signed into law the NASA Transition Act of 2017. The TREAT Astronauts Act, which is part of the NASA Transition Act

of 2017, gives NASA the authority to provide former U.S. Government astronauts and payload specialists medical monitoring and diagnosis for conditions that are potentially spaceflight associated and treatment for conditions that are spaceflight associated.

As directed by Congress in section 443 of Public Law No. 115-10, NASA first entered into an arrangement with an independent external organization to undertake an independent estimate of the cost to the Administration and the Federal Government to implement and administer activities under the TREAT Astronauts Act. This cost estimate was submitted to both the House Science, Space and Technology Committee and the Senate Commerce, Science and Transportation Committee on March 14, 2018. NASA also, as directed by Congress, carried out a study on any potential privacy or legal issues related to the possible sharing beyond the Federal Government of data acquired under the TREAT Astronauts Act. This was submitted to both the House Science, Space and Technology Committee and the Senate Commerce, Science and Transportation Committee on January 2, 2018. With the completion of these reports, NASA then began drafting these regulations.

In drafting these regulations, NASA officials met with former U.S. Government astronauts and payload specialists, as discussed more fully above. NASA also met with officials from the Department of Labor, Department of Veterans' Affairs, and the Defense Health Agency, critical partner agencies, who have an important stake in the outcome, on how best to collaborate and how to implement any required data sharing agreements.

***Good Cause.*** To establish a good cause exception to the APA requirement to publish a proposed rule, an Agency must show that notice would be either impracticable, unnecessary, or contrary to the public interest. *See* 5 U.S.C. 553(b)(B). An agency is further required to establish good cause for publishing a substantive rule less than 30 days before its effective date.

*See* 5 U.S.C. 553(d)(3). NASA believes that publication of a proposed rule is unnecessary and that there is good cause for the effective date of this rule to be less than 30 days after the date of publication.

Human space exploration poses significant challenges and is full of risk. With more recent long-duration space flight missions, NASA has seen the increased health risks that current U.S. Government astronauts face, such as vision impairment, bone demineralization, and exposure to radiation. NASA has also seen the increased health risks that former U.S. Government astronauts and payload specialists face, many years after their NASA service. Consequently, it is critical that NASA move forward with this rule without delay to ensure claims that are associated with human spaceflight are fully covered.

One of the vital tools NASA needs to prepare for future long-duration and exploration missions is data on the health effects human face in spaceflight. NASA needs these data to better understand the physical, behavioral, microbiological, and reaction on the molecular level of the human body to an extended period of time in space. Former U.S. Government astronauts and payload specialists who voluntarily participate in this program will be consenting to providing their medical data to NASA. Given the fact that there are so few astronauts and such limited data, increased participation to get more data is critical. NASA is learning daily of the untoward effects of human spaceflight on the human body. In order to prepare for the Moon in 2024, NASA needs to understand these effects so that we can take appropriate mitigation measures now.

As discussed more fully above, it is critical for NASA to start treating former U.S. Government astronauts and payload specialists for medical conditions that we are now beginning to understand many years later may be the results of their prior space flight exposure. We have

also learned more recently of the urgency of early diagnosis and treatment and that former astronauts may present symptoms differently than the general population. Due to the small population of astronauts, it is imperative that we increase our collection of data immediately so that we can utilize it to mitigate the risks of spaceflight to future and current astronauts and take care of those former astronauts with conditions associated with spaceflight. Since Astronaut Scott Kelly's 2015–2016 record year in space, nineteen astronauts have participated in longer space duration flights of up to one year, and NASA's goal is to return to the Moon by 2024. By increasing the population of former astronauts who are being monitored, NASA will be able to better understand the effects of space flight and institute ameliorative measures.

The unnecessary prong of the good cause inquiry is “confined to those situations in which the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and the public. *See Mack Trucks, Inc., v. EPA.*, 682 F.3d 87, 94 (D.C. Cir. 2012). This new rule applies only to a very limited and easily discernable group of beneficiaries—approximately 250 former U.S. Government astronauts and payload specialists. It does not affect any other member of the public in any significant way and, therefore, advanced notice is unnecessary.<sup>1</sup>

The Agency has also established good cause for dispensing with the 30-day delay in the effective date in accordance with 5 U.S.C. 553(d)(3). Unlike the notice and comment requirements, which are designed to ensure public participation in rulemaking, the 30-day waiting period is intended to give affected parties time to adjust their behavior before the final rule takes effect. Given the limited number of parties affected by the new rule, the facts that

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<sup>1</sup> As discussed above, the Agency believes that actual notice has been provided to former astronauts rendering the publication requirement of the APA unnecessary.

participation is voluntary and those impacted would like to be treated immediately, the urgency of the matter, and the discussion above, good cause has been shown.

For these reasons, the Agency will publish this rule without prior opportunity for public comment and with an immediate effective date. Thus, the Administrator issues this rule as an interim final rule with request for comments.

### **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 a significant regulatory action and has 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 expected to be an EO 13771 regulatory action because this rule is expected to be related to agency organization, management, or personnel.

### **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**

Health, medical, astronaut.

For reasons set forth in the preamble, NASA adds part 1241 to 14 CFR chapter V to read as follows:

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

### **ASTRONAUTS**

Sec.

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Authority: 51 U.S.C. 20149

**§ 1241.05 Purpose and scope**

(a) This part establishes a program and sets out the eligibility requirements and procedures to effectuate section 443 of the “To Research, Evaluate, Assess, and Treat Astronauts Act of 2017.”

(b) The purpose of this program is to provide medical monitoring and diagnosis of former U.S. Government astronauts and payload specialists for conditions the Administrator considers potentially associated with spaceflight and to provide treatment of former U.S. Government astronauts and payload specialists for conditions the Administrator considers associated with spaceflight.

**§ 1241.10 Covered medical care**

(a) Subject to the limitations in paragraph (b) of this section, an eligible individual, as defined in § 1241.15, is eligible for:

- (1) Monitoring and diagnosis for potentially spaceflight-associated conditions; and
- (2) Treatment for spaceflight-associated conditions.

(b) Medical monitoring, diagnosis, and treatment authorized and described in paragraph (a) of this section will not be provided for any condition that is found by the NASA Administrator or designee to have resulted from a cause other than the eligible individual’s participation in spaceflight-related activities. Should a condition be diagnosed that is not related to spaceflight, the individual will be referred to their primary care physician.

(c) Medical monitoring, diagnosis, and treatment authorized and described in paragraph (a) of this section may be provided by a local health care provider if the NASA Administrator or designee determines it is unadvisable for the eligible individual to travel to the NASA Johnson

Space Center (JSC) due to the individual's condition or if it is otherwise advantageous to the Government.

(d) Medical monitoring, diagnosis, and treatment authorized and described in paragraph (a) of this section will be provided without a cost sharing obligation imposed on the eligible individual.

(e) NASA is a secondary payer.

### **§ 1241.15 Definitions**

*Conditional Payment* means a NASA payment to a medical provider or eligible individual to pay for the cost of medical monitoring, diagnosis, and treatment. Such conditional payments may be made prior to a formal determination that a psychological or medical condition is spaceflight-associated if payment has not been made or cannot reasonably be expected to be made promptly by the primary payer.

*Cost Sharing* means a multiparty arrangement under which costs of a program are shared by the involved parties, according to an agreed upon formula. For this program, there is no cost sharing obligation by the eligible individual. The eligible individual is responsible for insurance premiums.

*Diagnosis* means the identification of a medical or psychological condition consistent with the exercise of professional clinical judgment and accepted standard of care by licensed health professionals.

*Eligible Individual* means a former United States Government astronaut, including a member of the Uniformed Services, or a former payload specialist who has flown in space, as defined in the TREAT Astronauts Act. The following individuals are specifically excluded from eligible individuals:

- (1) Astronauts of other United States Government agencies;
- (2) Employees of commercial spaceflight companies who were never employed by NASA nor a member of the Uniformed Services assigned to NASA;
- (3) International partner astronauts;
- (4) Employees of foreign governments;
- (5) Private individuals or tourists who have flown in space; and
- (6) Former astronauts, including members of the Uniformed Services, and former payload specialists who have not flown in space.

*JSC* means Johnson Space Center.

*Monitoring* means the NASA astronaut spaceflight exposure clinical assessment of medical and psychological health status by licensed health professionals.

*Payload Specialist* means an individual other than a NASA astronaut (commander, pilot, and mission specialist) whose presence was required onboard the space shuttle vehicle to perform specialized functions with respect to operation of one or more payloads or other essential mission activities.

*Primary Payer* means the entity, U.S. Government agency or private health insurer, which is responsible to make payment to the eligible individual first, up to the limits of its coverage or authority.

*Program* means the medical monitoring, diagnosis, and treatment authorized by the TREAT Astronauts Act.

*Secondary Payer* means the entity that pays after all primary payers have paid, up to the limits of their coverage. Secondary payments, as described in the TREAT Astronauts Act, are payments or reimbursement for the medical monitoring, diagnosis, or treatment secondary to any

obligation of the U.S. Government or any third party under any other provision of law or contractual agreement to pay for or provide such medical monitoring, diagnosis, or treatment.

*Spaceflight-Associated Condition* means a medical or psychological condition that the NASA Administrator or designee designated by the NASA Administrator determines is at least as likely as not to have resulted from participation in spaceflight-related activities.

*Treatment* means the accepted standard of clinical care for a medical or psychological condition by licensed health professionals.

*TREAT Astronauts Act* means section 443 of the “To Research, Evaluate, Assess, and Treat Astronauts Act of 2017.”

*TREAT Astronauts Act Board or TAAB* means the internal NASA review board that provides recommendations to the NASA Administrator or designee as to whether or not a medical claim initiated by an eligible individual meets the standards for spaceflight association for medical monitoring, diagnosis, and treatment under the TREAT Astronauts Act.

*U.S. Government Agency* means “agency” as defined in 5 U.S.C. 551.

## **§ 1241.20 Eligibility**

(a) This section sets forth those persons who, by the provisions of the TREAT Astronauts Act, are eligible to participate in this program. A determination by the Administrator or designee that a person is eligible does not automatically entitle such a person to medical monitoring, diagnosis, and treatment under the TREAT Astronauts Act.

(b) Only eligible individuals defined in § 1241.15 are entitled to medical monitoring, diagnosis, and treatment under this part.

(c) Participation in this program is strictly voluntary. NASA may not require an eligible individual to participate in this program.

## § 1241.25 Basic program

(a) *General--(1) Scope.* Subject to all applicable definitions, conditions, limitations, or exclusions specified in this part, NASA will provide medical monitoring and diagnosis of potentially spaceflight-associated conditions and treatment of a spaceflight-associated conditions, as well as any associated travel expenses for the eligible individual's lifetime.

(2) *Location of medical monitoring, diagnosis, and treatment.* (i) Medical monitoring will be provided for eligible individuals at the JSC.

(ii) When travel is inadvisable due to the health of the eligible individual or when otherwise advantageous to the Government, monitoring may be provided at a location other than the JSC.

(iii) Diagnosis and treatment will be provided for eligible individuals at locations determined by the medical appropriateness of the facility, patient preferences, cost effectiveness, and other pertinent factors.

(3) *Right to information.* As a condition precedent to participation in this program, NASA is entitled to receive copies of medical records from any physician, hospital or other person, health insurance company, institution, or entity (including a local, state, or U.S. Government agency) providing medical monitoring, diagnosis, and treatment to the eligible individual for which claims or requests for approval for medical monitoring, diagnosis, and treatment are submitted to NASA. As part of this condition precedent, NASA may require eligible individuals to complete such medical releases needed to facilitate obtaining such information as legally required by state and Federal law.

(b) *Monitoring and Diagnosis.* NASA will provide monitoring and diagnosis for eligible individuals for conditions potentially associated with spaceflight.

(1) Standardized monitoring will be offered routinely at the JSC.

(2) Individualized monitoring will be provided, as necessary.

(3) NASA may pay for and obtain autopsies of eligible individuals, who previously consented in writing or with consent of the next of kin, when such autopsy would contribute substantially to the knowledge of spaceflight physiology or pathology. NASA will coordinate with the Armed Forces Medical Examiner System for such autopsies.

(c) *Treatment.* NASA will provide or arrange for the treatment of spaceflight-associated conditions.

(1) Treatment will be secondary to any services provided by primary payers.

(2) Should urgency dictate, NASA may provide for conditional payments for treatment.

(d) *Exclusions and limitations.* In addition to any definitions, requirements, conditions, or limitations enumerated and described in other sections of this part, the following are specifically excluded:

(1) Medical monitoring or diagnosis of an eligible individual for any medical or psychological condition that is not potentially associated with human spaceflight; and

(2) Treatment of an eligible individual for any medical or psychological condition that is not associated with human spaceflight.

### **§ 1241.30 Program participation and claims submission**

(a) *General program participation.* An eligible individual, or their authorized representative, who seek to participate in this program must provide the information set forth in paragraph (e)(2) of this section to NASA. The JSC Flight Medicine Clinic will assist eligible individuals through these processes.

(b) *NASA's occupationally related medical monitoring services.* (1) Eligible individuals will receive an annual invitation from NASA to participate in NASA's occupational surveillance program;

(2) [Reserved]

(c) *Primary payer coverage of diagnosis and treatment services.* (1) *Former Civil Servants.* Eligible individuals who were civil servant employees during their active astronaut or payload specialist career who believe they have sustained a spaceflight-associated condition and are seeking coverage for medical treatment under this part must submit a notice of injury and claim for compensation through their agency to the Department of Labor, Office of the Workers' Compensation Programs Division of Federal Employees' Compensation (DFEC) consistent with 5 U.S.C. Chapter 81 and 20 CFR part 10 before making a claim under the TREAT Astronauts Act.

(2) *Members of the Uniformed Services.* Eligible individuals who were members of the Uniformed Services during their active astronaut or payload specialist career, or who are otherwise determined to be eligible by their Uniformed Service and who believe they have sustained a spaceflight-associated condition must contact their Service to determine eligibility for health and dental care and/or coverage through the Military Health System of the Department of Defense, consistent with 10 U.S.C. Chapter 55 and 32 CFR part 199 before making a claim under the TREAT Astronauts Act.

(3) *Former Civil Servants who were also Members of the Uniformed Services.* Eligible individuals whose active astronaut career spanned both military and civil service will first submit a notice to the Department of Labor who will work with the Department of Defense.

(4) *Eligible individuals with claims denied or partially covered.* If the eligible individual's claim under paragraphs (c)(1), (2), or (3) of this section is either denied or covered only in part by the primary payer, the eligible individual can apply for medical monitoring, diagnosis, and treatment under this program.

(d) *Diagnosis and Treatment or Other Benefits-Veterans.* An eligible individual who is enrolled, or eligible to be enrolled, in the U.S. Department of Veterans Affairs (VA) health care system may opt instead to seek his or her care and services through the VA. Under the TREAT Astronauts program, the eligible individual may seek reimbursement from NASA for any out-of-pocket copayment(s) he or she paid to VA for care of a condition that NASA determines is associated with spaceflight. The individual may also apply for disability compensation with the Department of Veterans Affairs, Veterans Benefits Administration, pursuant to 38 CFR part 3.

(e) *Submitting claims for medical monitoring, diagnosis, and treatment under this program--*

(1) *Claim required.* (i) No medical diagnosis and treatment may be extended under the TREAT Astronauts Act without submission of a complete claim form to the JSC Flight Medicine Clinic.

(ii) NASA will provide specific forms appropriate for making a claim for medical monitoring, diagnosis, and treatment. Claim forms may be obtained from the JSC Flight Medicine Clinic. Contact information can be found at: <https://www.nasa.gov/hhp/treat-act>.

(2) *Information required.* Each claim for medical monitoring, diagnosis, and treatment under this program will be in writing and include, at a minimum:

(i) Statement of eligibility describing the employment and spaceflight history that justifies medical monitoring, diagnosis, and treatment under this program;

(ii) History and diagnosis of medical or psychological condition;

(iii) Medical documentation in support of the claim. Healthcare providers must be licensed and permitted to practice under state law and not be on the Centers for Medicare & Medicaid Services (CMS) List of Excluded Individuals and Entities, found at: <https://healthdata.gov/dataset/list-excluded-individuals-and-entities>;

(iv) Documentation of the decisions and/or payments made by the primary payer (i.e., other U.S. Government agencies and/or private health insurer) regarding the claim;

(v) Justification for determination that the psychological or medical condition is associated with spaceflight;

(vi) Expenses for which they are seeking reimbursement, to include documentation of all out-of-pocket costs; and

(vii) The signature of the eligible individual or their authorized representative.

(3) *Responsibility for perfecting claim.* It is the responsibility of the eligible individual, authorized representative, or the authorized provider acting on behalf of the eligible individual to perfect a claim for submission. NASA will assist eligible individuals with claims submission, but is not authorized to prepare a claim on behalf of the eligible individual.

#### **§ 1241.35 Claims review and decisions**

(a) NASA will establish the TREAT Astronauts Act Board (TAAB) to review claims for medical monitoring, diagnosis, and treatment under this program. This review is independent of any review conducted by primary payers.

(b) The TAAB will review each claim submitted by the eligible individual, in consultation with specialists, as appropriate. A typical case will be reviewed within 30 calendar days, but cases that are more complex may take additional time.

(c) The TAAB will make a recommendation to the Administrator or designee for each claim stating whether the condition is determined to be spaceflight associated.

(d) For those eligible individuals who have had other exposures in addition to those experienced during their career as active U.S. Government astronauts or payload specialists, the TAAB will consider that history when making its recommendation.

(e) The NASA Administrator or designee will review each claim and associated TAAB recommendation to determine whether the claim should be approved or denied. A typical case can be reviewed within 30 calendar days, but cases that are more complex may take additional time.

(f) The decision will be provided to the eligible individual within seven calendar days of the final decision by the NASA Administrator or designee. Decisions not in favor of the eligible individual will include information on how to request reconsideration.

(g) An eligible individual or their authorized representative may request reconsideration of the decision at any time if new information is obtained that enhances the claim. Reconsideration requests can be made to the JSC Flight Medicine Clinic.

(h) Requests for reconsideration are reviewed by the TAAB and decisions made by the Administrator or designee, following the same process described in paragraphs (b) through (f) of this section.

#### **§ 1241.40 Payment of approved claims**

(a) The NASA Administrator or designee is responsible for ensuring that medical monitoring, diagnosis, and treatment to eligible individuals under this program is paid only to the extent described in this part.

(b) Payment for medical monitoring, diagnosis, and treatment is applied secondarily to primary payers and may include the remaining out-of-pocket costs from primary payer coverage.

(c) NASA will pay necessary travel expenses related to this program consistent with the Federal Travel Regulations.

(d) NASA may provide conditional payments for medical monitoring, diagnosis, and treatment that is obligated to be paid by the U.S. Government or other primary payers prior to a final decision by NASA in accordance with § 1241.35. Such requests for conditional payments can be made to JSC Flight Medicine Clinic. Such payments are permitted when payment for such medical monitoring, diagnosis, and treatment has either not been made or will not be made promptly.

(1) NASA may seek to recover costs associated with conditional payments from the U.S. Government, private health insurance company, or other primary payer as allowable by law.

(2) If the claim is denied in accordance with § 1241.35, NASA may seek to recover such conditional payments from the eligible individual in accordance with 31 U.S.C. Chapter 37.

#### **§ 1241.45 Collaboration with other agencies**

Copies of records generated from medical monitoring, diagnosis, and treatment collected by primary payer facilities and/or relevant health care providers will be acquired by NASA. NASA will collaborate with the Department of Defense Military Health System, Department of Veterans Affairs, and Department of Labor Office of Workers' Compensation and other entities for acquisition of copies of these medical records as allowed by law.

#### **§ 1241.50 Records, confidentiality, privacy, and data use**

(a) Records on individuals created or obtained pursuant to this regulation that are subject to the Privacy Act of 1974, as amended, 5 U.S.C 552a, will be maintained in accordance with the NASA's Privacy Act System of Records.

(b) NASA will, as necessary, enter into data sharing agreements with other agencies and/or entities to receive such data and/or seek signed medical releases from the eligible individuals, or their authorized representatives, in accordance with law.

(c) NASA's collection, use, and disclosure of this data will be in accordance with the Privacy Act of 1974, NASA's implementing regulations at 14 CFR part 1212, and NASA's privacy policies, where applicable.

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NASA Directives and Regulations.

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