

ACCESS TO LIFE-SAVING TRAUMA CARE FOR ALL  
 AMERICANS ACT

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MARCH 16, 2015.—Committed to the Committee of the Whole House on the State  
 of the Union and ordered to be printed

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Mr. UPTON, from the Committee on Energy and Commerce,  
 submitted the following

R E P O R T

[To accompany H.R. 647]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred  
 the bill (H.R. 647) to amend title XII of the Public Health Service  
 Act to reauthorize certain trauma care programs, and for other  
 purposes, having considered the same, report favorably thereon  
 without amendment and recommend that the bill do pass.

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## PURPOSE AND SUMMARY

H.R. 647, Access to Life-Saving Trauma Care for All Americans Act was introduced on February 2, 2015, by Rep. Michael Burgess (R-TX) and Rep. Gene Green (D-TX) and referred to the Committee on Energy and Commerce. The legislation is intended to support and prevent further trauma center closures and would amend the Public Health Service Act (PHSA) to establish three grant programs: (1) Substantial Uncompensated Care Awards; (2) Core Mission Awards; and (3) Emergency Awards.

## BACKGROUND AND NEED FOR LEGISLATION

Trauma centers should be available for all victims of traumatic injury. Getting a trauma victim to a trauma center right away is the first step in saving his or her life. Unfortunately, many trauma centers are at serious risk of closure and financial insolvency.

In addition, the supply of trauma surgeons in the United States is rapidly declining, and the pipeline to replace retiring trauma surgeons and surgical specialists is limited. As a result of this shortage, and other factors, an increasing number of trauma centers are closing or downgrading their trauma center designation level due to factors that include a lack of access to on-call trauma specialists.

The public's expectation that trauma care will always be available to them wherever they reside or travel has yet to be met. Nearly thirty trauma centers have closed in the past fifteen years, which has limited the availability of critical trauma care in several States.

H.R. 647 will provide critically needed resources to offset uncompensated costs in trauma centers, support core mission trauma services, provide emergency funding to trauma centers, and address trauma center physician shortages in order to ensure the future availability of trauma care for all our citizens.

## HEARINGS

The Subcommittee on Health held a hearing on H.R. 647 on January 27, 2015, and the Subcommittee received testimony from Blaine L. Enderson, MD, Department of Surgery, University of Tennessee Medical Center.

## COMMITTEE CONSIDERATION

On February 4, 2015, the Subcommittee on Health met in open markup session to consider a Committee Print entitled "Access to Life-Saving Trauma Care for All Americans Act" and forwarded the Committee Print to the full Committee, without amendment, by a voice vote. On February 11 and 12, 2015, the full Committee met in open markup session to consider H.R. 647, which was substantially similar to the Committee Print forwarded by the Subcommittee, and ordered the bill favorably reported to the House, without amendment, by a voice vote.

## COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion

to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 647 reported. A motion by Mr. Upton to order H.R. 647 reported to the House, without amendment, was agreed to by a voice vote.

#### COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held a hearing and made findings, which are reflected throughout this report.

#### STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

H.R. 647 is intended to support and prevent trauma center grant closures by establishing three grant programs: Substantial Uncompensated Care Awards, Core Mission Awards; and Emergency Awards.

#### NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 647, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

#### EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI of the Rules of the House of Representatives, the Committee finds that H.R. 647 contains no earmarks, limited tax benefits, or limited tariff benefits.

#### COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

#### CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,  
CONGRESSIONAL BUDGET OFFICE,  
*Washington, DC, March 11, 2015.*

Hon. FRED UPTON,  
*Chairman, Committee on Energy and Commerce,  
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 647, the Access to Life-Saving Trauma Care for All Americans Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Zoë Williams.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

*H.R. 647—Access to Life-Saving Trauma Care for All Americans Act*

Summary: H.R. 647 would amend the Public Health Service Act to authorize funding for grant programs that support trauma care centers and trauma service availability. The bill also would clarify that public, nonprofit, Indian Health Service, Indian tribal, and urban Indian trauma centers are eligible to receive grants, and would change the administration of those grant programs to be the responsibility of the Assistant Secretary for Preparedness and Response.

The bill would authorize the appropriation of \$100 million a year for each of fiscal years 2016 through 2020. CBO estimates that implementing the bill would cost \$401 million over the 2016–2020 period, assuming appropriation of the authorized amounts. Pay-as-you-go procedures do not apply to this legislation because it would not affect direct spending or revenues.

H.R. 647 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

Estimated cost to the Federal Government: For this estimate, CBO assumes that H.R. 647 will be enacted by the start of fiscal year 2016, the Congress will appropriate the authorized amounts for each year, and spending will follow historical patterns for similar programs. The estimated budgetary effects of H.R. 647 are shown in the following table. The costs of this legislation fall within budget function 550 (health).

|  | By fiscal year, in millions of dollars— |      |      |      |      |           |
|--|---|------|------|------|------|-----------|
|  | 2016                                    | 2017 | 2018 | 2019 | 2020 | 2016-2020 |
| CHANGES IN SPENDING SUBJECT TO APPROPRIATION |   |      |      |      |      |           |
| Authorization Level .....                    | 100                                     | 100  | 100  | 100  | 100  | 500       |
| Estimated Outlays .....                      | 25                                      | 84   | 94   | 98   | 100  | 401       |

Pay-As-You-Go considerations: None.

Intergovernmental and private-sector impact: H.R. 647 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

Estimate prepared by: Federal costs: Zoë Williams; Impact on state, local, and tribal governments: J'nell Blanco Suchy; Impact on the private sector: Amy Petz.

Estimate approved by: Holly Harvey, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

#### DUPPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 647 establishes or reauthorizes a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

#### DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 647 specifically directs to be completed 0 rule makings within the meaning of 5 U.S.C. 551.

#### ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

#### APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

#### SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

##### *Section 1. Short title*

Section 1 provides the short title “Access to Life-Saving Trauma Care for All Americans Act.”

##### *Section 2. Reauthorization of Trauma and Emergency Care Programs*

Section 2 reauthorizes the Trauma Care Center Grants and the Trauma Service Availability Grants in section 1245 of the Public Health Service act at previously authorized levels.

##### *Section 3. Alignment of programs under Assistant Secretary of Preparedness and Response*

This section consolidates existing Federal trauma programs under the Assistant Secretary for Preparedness and Response.

##### *Section 4. Technical clarifications relating to Trauma Center Grants*

This section clarifies that nonprofit trauma centers are eligible for the Trauma Care Center Grants.

#### CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

**PUBLIC HEALTH SERVICE ACT**

\* \* \* \* \*

TITLE XII—TRAUMA CARE

\* \* \* \* \*

**[PART D—TRAUMA CENTERS OPERATING IN AREAS SEVERELY  
AFFECTED BY DRUG-RELATED VIOLENCE]**

***PART D—TRAUMA CENTERS***

**SEC. 1241. GRANTS FOR CERTAIN TRAUMA CENTERS.**

(a) **IN GENERAL.**—The Secretary shall establish 3 programs to award grants to **[qualified public, nonprofit Indian Health Service, Indian tribal, and urban Indian trauma centers]** *qualified public trauma centers, qualified nonprofit trauma centers, and qualified Indian Health Service, Indian tribal, and urban Indian trauma centers*—

(1) to assist in defraying substantial uncompensated care costs;

(2) to further the core missions of such trauma centers, including by addressing costs associated with patient stabilization and transfer, trauma education and outreach, coordination with local and regional trauma systems, essential personnel and other fixed costs, and expenses associated with employee and non-employee physician services; and

(3) to provide emergency relief to ensure the continued and future availability of trauma services.

(b) **MINIMUM QUALIFICATIONS OF TRAUMA CENTERS.**—

(1) **PARTICIPATION IN TRAUMA CARE SYSTEM OPERATING UNDER CERTAIN PROFESSIONAL GUIDELINES.**—Except as provided in paragraph (2), the Secretary may not award a grant to a trauma center under subsection (a) unless the trauma center is a participant in a trauma system that substantially complies with section 1213.

(2) **EXEMPTION.**—Paragraph (1) shall not apply to trauma centers that are located in States with no existing trauma care system.

(3) **QUALIFICATION FOR SUBSTANTIAL UNCOMPENSATED CARE COSTS.**—The Secretary shall award substantial uncompensated care grants under subsection (a)(1) only to trauma centers meeting at least 1 of the criteria in 1 of the following 3 categories:

(A) **CATEGORY A.**—The criteria for category A are as follows:

(i) At least 40 percent of the visits in the emergency department of the hospital in which the trauma center is located were charity or self-pay patients.

(ii) At least 50 percent of the visits in such emergency department were Medicaid (under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.)) and charity and self-pay patients combined.

(B) **CATEGORY B.**—The criteria for category B are as follows:

(i) At least **[35]** 30 percent of the visits in the emergency department were charity or self-pay patients.

(ii) At least **[50]** 40 percent of the visits in the emergency department were Medicaid and charity and self-pay patients combined.

(C) CATEGORY C.—The criteria for category C are as follows:

(i) At least 20 percent of the visits in the emergency department were charity or self-pay patients.

(ii) At least 30 percent of the visits in the emergency department were Medicaid and charity and self-pay patients combined.

(4) TRAUMA CENTERS IN 1115 WAIVER STATES.—Notwithstanding paragraph (3), the Secretary may award a substantial uncompensated care grant to a trauma center under subsection (a)(1) if the trauma center qualifies for funds under a Low Income Pool or Safety Net Care Pool established through a waiver approved under section 1115 of the Social Security Act (42 U.S.C. 1315).

(5) DESIGNATION.—The Secretary may not award a grant to a trauma center unless such trauma center is verified by the American College of Surgeons or designated by an equivalent State or local agency.

(c) ADDITIONAL REQUIREMENTS.—The Secretary may not award a grant to a trauma center under subsection (a)(1) unless such trauma center—

(1) submits to the Secretary a plan satisfactory to the Secretary that demonstrates a continued commitment to serving trauma patients regardless of their ability to pay; and

(2) has policies in place to assist patients who cannot pay for part or all of the care they receive, including a sliding fee scale, and to ensure fair billing and collection practices.

\* \* \* \* \*

**SEC. 1245. AUTHORIZATION OF APPROPRIATIONS.**

For the purpose of carrying out this part, there are authorized to be appropriated \$100,000,000 for fiscal year **[2009, and such] 2009, such** sums as may be necessary for each of fiscal years 2010 through 2015, *and \$100,000,000 for each of fiscal years 2016 through 2020.* Such authorization of appropriations is in addition to any other authorization of appropriations or amounts that are available for such purpose.

\* \* \* \* \*

**PART H—TRAUMA SERVICE AVAILABILITY**

\* \* \* \* \*

**SEC. 1282. AUTHORIZATION OF APPROPRIATIONS.**

For the purpose of carrying out this part, there is authorized to be appropriated \$100,000,000 for each of fiscal years 2010 through **[2015] 2020.**

\* \* \* \* \*

**TITLE XXVIII—NATIONAL ALL-HAZARDS  
PREPAREDNESS FOR PUBLIC HEALTH  
EMERGENCIES**

\* \* \* \* \*

**Subtitle B—All-Hazards Emergency  
Preparedness and Response**

**SEC. 2811. COORDINATION OF PREPAREDNESS FOR AND RESPONSE  
TO ALL-HAZARDS PUBLIC HEALTH EMERGENCIES.**

(a) **IN GENERAL.**—There is established within the Department of Health and Human Services the position of the Assistant Secretary for Preparedness and Response. The President, with the advice and consent of the Senate, shall appoint an individual to serve in such position. Such Assistant Secretary shall report to the Secretary.

(b) **DUTIES.**—Subject to the authority of the Secretary, the Assistant Secretary for Preparedness and Response shall carry out the following functions:

(1) **LEADERSHIP.**—Serve as the principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies.

(2) **PERSONNEL.**—Register, credential, organize, train, equip, and have the authority to deploy Federal public health and medical personnel under the authority of the Secretary, including the National Disaster Medical System, and coordinate such personnel with the Medical Reserve Corps and the Emergency System for Advance Registration of Volunteer Health Professionals.

(3) **COUNTERMEASURES.**—Oversee advanced research, development, and procurement of qualified countermeasures (as defined in section 319F-1), security countermeasures (as defined in section 319F-2), and qualified pandemic or epidemic products (as defined in section 319F-3).

(4) **COORDINATION.**—

(A) **FEDERAL INTEGRATION.**—Coordinate with relevant Federal officials to ensure integration of Federal preparedness and response activities for public health emergencies.

(B) **STATE, LOCAL, AND TRIBAL INTEGRATION.**—Coordinate with State, local, and tribal public health officials, the Emergency Management Assistance Compact, health care systems, and emergency medical service systems to ensure effective integration of Federal public health and medical assets during a public health emergency.

(C) **EMERGENCY MEDICAL SERVICES.**—Promote improved emergency medical services medical direction, system integration, research, and uniformity of data collection, treatment protocols, and policies with regard to public health emergencies.

(D) **POLICY COORDINATION AND STRATEGIC DIRECTION.**—Provide integrated policy coordination and strategic direction with respect to all matters related to Federal public health and medical preparedness and execution and de-

ployment of the Federal response for public health emergencies and incidents covered by the National Response Plan developed pursuant to section 504(6) of the Homeland Security Act of 2002, or any successor plan, before, during, and following public health emergencies.

(E) IDENTIFICATION OF INEFFICIENCIES.—Identify and minimize gaps, duplication, and other inefficiencies in medical and public health preparedness and response activities and the actions necessary to overcome these obstacles.

(F) COORDINATION OF GRANTS AND AGREEMENTS.—Align and coordinate medical and public health grants and cooperative agreements as applicable to preparedness and response activities authorized under this Act, to the extent possible, including program requirements, timelines, and measurable goals, and in consultation with the Secretary of Homeland Security, to—

(i) optimize and streamline medical and public health preparedness and response capabilities and the ability of local communities to respond to public health emergencies; and

(ii) gather and disseminate best practices among grant and cooperative agreement recipients, as appropriate.

(G) DRILL AND OPERATIONAL EXERCISES.—Carry out drills and operational exercises, in consultation with the Department of Homeland Security, the Department of Defense, the Department of Veterans Affairs, and other applicable Federal departments and agencies, as necessary and appropriate, to identify, inform, and address gaps in and policies related to all-hazards medical and public health preparedness and response, including exercises based on—

(i) identified threats for which countermeasures are available and for which no countermeasures are available; and

(ii) unknown threats for which no countermeasures are available.

(H) NATIONAL SECURITY PRIORITY.—On a periodic basis consult with, as applicable and appropriate, the Assistant to the President for National Security Affairs, to provide an update on, and discuss, medical and public health preparedness and response activities pursuant to this Act and the Federal Food, Drug, and Cosmetic Act, including progress on the development, approval, clearance, and licensure of medical countermeasures.

(5) LOGISTICS.—In coordination with the Secretary of Veterans Affairs, the Secretary of Homeland Security, the General Services Administration, and other public and private entities, provide logistical support for medical and public health aspects of Federal responses to public health emergencies.

(6) LEADERSHIP.—Provide leadership in international programs, initiatives, and policies that deal with public health and medical emergency preparedness and response.

(7) COUNTERMEASURES BUDGET PLAN.—Develop, and update on an annual basis, a coordinated 5-year budget plan based on

the medical countermeasure priorities described in subsection (d). Each such plan shall—

(A) include consideration of the entire medical countermeasures enterprise, including—

(i) basic research and advanced research and development;

(ii) approval, clearance, licensure, and authorized uses of products; and

(iii) procurement, stockpiling, maintenance, and replenishment of all products in the Strategic National Stockpile;

(B) inform prioritization of resources and include measurable outputs and outcomes to allow for the tracking of the progress made toward identified priorities;

(C) identify medical countermeasure life-cycle costs to inform planning, budgeting, and anticipated needs within the continuum of the medical countermeasure enterprise consistent with section 319F–2; and

(D) be made available to the appropriate committees of Congress upon request.

(c) FUNCTIONS.—The Assistant Secretary for Preparedness and Response shall—

(1) have lead responsibility within the Department of Health and Human Services for emergency preparedness and response policy coordination and strategic direction;

(2) have authority over and responsibility for—

(A) the National Disaster Medical System pursuant to section 2812;

(B) the Hospital Preparedness Cooperative Agreement Program pursuant to section 319C–2;

(C) the Biomedical Advanced Research and Development Authority pursuant to section 319L;

(D) the Medical Reserve Corps pursuant to section 2813;

(E) the Emergency System for Advance Registration of Volunteer Health Professionals pursuant to section 319I; and

(F) administering grants and related authorities related to **trauma care under parts A through C of title XII** *trauma care under parts A through D of title XII and part H of such title*, such authority to be transferred by the Secretary from the Administrator of the Health Resources and Services Administration to such Assistant Secretary;

(3) exercise the responsibilities and authorities of the Secretary with respect to the coordination of—

(A) the Public Health Emergency Preparedness Cooperative Agreement Program pursuant to section 319C–1;

(B) the Strategic National Stockpile pursuant to section 319F–2; and

(C) the Cities Readiness Initiative; and

(4) assume other duties as determined appropriate by the Secretary.

(d) PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES ENTERPRISE STRATEGY AND IMPLEMENTATION PLAN.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of this subsection, and every year thereafter, the

Assistant Secretary for Preparedness and Response shall develop and submit to the appropriate committees of Congress a coordinated strategy and accompanying implementation plan for medical countermeasures to address chemical, biological, radiological, and nuclear threats. In developing such a plan, the Assistant Secretary for Preparedness and Response shall consult with the Director of the Biomedical Advanced Research and Development Authority, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs. Such strategy and plan shall be known as the “Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan”.

(2) REQUIREMENTS.—The plan under paragraph (1) shall—

(A) describe the chemical, biological, radiological, and nuclear agent or agents that may present a threat to the Nation and the corresponding efforts to develop qualified countermeasures (as defined in section 319F–1), security countermeasures (as defined in section 319F–2), or qualified pandemic or epidemic products (as defined in section 319F–3) for each threat;

(B) evaluate the progress of all activities with respect to such countermeasures or products, including research, advanced research, development, procurement, stockpiling, deployment, distribution, and utilization;

(C) identify and prioritize near-, mid-, and long-term needs with respect to such countermeasures or products to address a chemical, biological, radiological, and nuclear threat or threats;

(D) identify, with respect to each category of threat, a summary of all awards and contracts, including advanced research and development and procurement, that includes—

(i) the time elapsed from the issuance of the initial solicitation or request for a proposal to the adjudication (such as the award, denial of award, or solicitation termination); and

(ii) an identification of projected timelines, anticipated funding allocations, benchmarks, and milestones for each medical countermeasure priority under subparagraph (C), including projected needs with regard to replenishment of the Strategic National Stockpile;

(E) be informed by the recommendations of the National Biodefense Science Board pursuant to section 319M;

(F) evaluate progress made in meeting timelines, allocations, benchmarks, and milestones identified under subparagraph (D)(ii);

(G) report on the amount of funds available for procurement in the special reserve fund as defined in section 319F–2(h) and the impact this funding will have on meeting the requirements under section 319F–2;

(H) incorporate input from Federal, State, local, and tribal stakeholders;

(I) identify the progress made in meeting the medical countermeasure priorities for at-risk individuals (as de-

fined in 2802(b)(4)(B)), as applicable under subparagraph (C), including with regard to the projected needs for related stockpiling and replenishment of the Strategic National Stockpile, including by addressing the needs of pediatric populations with respect to such countermeasures and products in the Strategic National Stockpile, including—

(i) a list of such countermeasures and products necessary to address the needs of pediatric populations;

(ii) a description of measures taken to coordinate with the Office of Pediatric Therapeutics of the Food and Drug Administration to maximize the labeling, dosages, and formulations of such countermeasures and products for pediatric populations;

(iii) a description of existing gaps in the Strategic National Stockpile and the development of such countermeasures and products to address the needs of pediatric populations; and

(iv) an evaluation of the progress made in addressing priorities identified pursuant to subparagraph (C);

(J) identify the use of authority and activities undertaken pursuant to sections 319F-1(b)(1), 319F-1(b)(2), 319F-1(b)(3), 319F-1(c), 319F-1(d), 319F-1(e), 319F-2(c)(7)(C)(iii), 319F-2(c)(7)(C)(iv), and 319F-2(c)(7)(C)(v) of this Act, and subsections (a)(1), (b)(1), and (e) of section 564 of the Federal Food, Drug, and Cosmetic Act, by summarizing—

(i) the particular actions that were taken under the authorities specified, including, as applicable, the identification of the threat agent, emergency, or the biomedical countermeasure with respect to which the authority was used;

(ii) the reasons underlying the decision to use such authorities, including, as applicable, the options that were considered and rejected with respect to the use of such authorities;

(iii) the number of, nature of, and other information concerning the persons and entities that received a grant, cooperative agreement, or contract pursuant to the use of such authorities, and the persons and entities that were considered and rejected for such a grant, cooperative agreement, or contract, except that the report need not disclose the identity of any such person or entity;

(iv) whether, with respect to each procurement that is approved by the President under section 319F-2(c)(6), a contract was entered into within one year after such approval by the President; and

(v) with respect to section 319F-1(d), for the one-year period for which the report is submitted, the number of persons who were paid amounts totaling \$100,000 or greater and the number of persons who were paid amounts totaling at least \$50,000 but less than \$100,000; and

(K) be made publicly available.

(3) GAO REPORT.—

(A) IN GENERAL.—Not later than 1 year after the date of the submission to the Congress of the first Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the appropriate committees of Congress a report, concerning such Strategy and Implementation Plan.

(B) CONTENT.—The report described in subparagraph (A) shall review and assess—

(i) the near-term, mid-term, and long-term medical countermeasure needs and identified priorities of the Federal Government pursuant to paragraph (2)(C);

(ii) the activities of the Department of Health and Human Services with respect to advanced research and development pursuant to section 319L; and

(iii) the progress made toward meeting the timelines, allocations, benchmarks, and milestones identified in the Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan under this subsection.

(e) PROTECTION OF NATIONAL SECURITY.—In carrying out subsections (b)(7) and (d), the Secretary shall ensure that information and items that could compromise national security, contain confidential commercial information, or contain proprietary information are not disclosed.

\* \* \* \* \*

