



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Renewal of Charters for Certain Federal Advisory Committees

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health

ACTION : Notice

SUMMARY: As stipulated by the Federal Advisory Committee Act, as amended (5 U.S.C. App), the U.S. Department of Health and Human Services is hereby announcing that the charters have been renewed for the following federal advisory committees for which Office of the Assistant Secretary for Health provides management support: Chronic Fatigue Syndrome Advisory Committee (CFSAC); President's Council on Fitness, Sports, and Nutrition (PCFSN; the Council); Secretary's Advisory Committee on Human Research Protections (SACHRP); and Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA). Functioning as federal advisory committees, these committees are governed by the provisions of the Federal Advisory Committee Act (FACA). Under FACA, it is stipulated that the charter for a federal advisory committee must be renewed every two years in order for the committee to continue to operate.

FOR FURTHER INFORMATION CONTACT: Olga B. Nelson, Committee Management Officer, Office of the Assistant Secretary for Health; U.S. Department of Health and Human

Services; 200 Independence Avenue, S.W., Room 714B; Washington, D.C. 20201; (202) 690-5205.

SUPPLEMENTARY INFORMATION: CFSAC was established on September 5, 2002 as a discretionary federal advisory committee. The Committee provides science-based advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on a broad range of issues and topics pertaining to myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), including (1) opportunities to improve knowledge and research about the epidemiology, etiologies, biomarkers and risk factors for ME/CFS; (2) research on the diagnosis, treatment, and management of ME/CFS and potential impact of treatment options; (3) strategies to inform the public, health care professionals, and the biomedical academic and research communities about ME/CFS advances; (4) partnerships to improve the quality of life of ME/CFS patients; and (5) strategies to insure that input from ME/CFS patients and care givers is incorporated into HHS policy and research.

The new charter includes the following amendments: (1) the language in the Description of Duties has been simplified. A fifth duty has been added to emphasize the importance of getting stakeholder input on HHS policy and research concerning ME/CFS; (2) authority has been given to the Assistant Secretary for Health (ASH) as an official to whom the Committee will report. Extending this authority to include the ASH gives clear responsibility to the ASH for better monitoring and implementation of the recommendations that are approved by the Secretary; and (3) the Committee structure has been changed to (a) increase the number of voting public

members to 13 to give patients and/or caretakers of ME/CFS more representation on the Committee. This amendment has been made to the charter to respond to recent concerns that had been expressed by CFS advocates, (b) remove the Centers for Medicare and Medicaid Services (CMS) as a non-voting *ex-officio* member. A determination was made that there is not much for CMS to contribute to or to seek advice from CFSAC. It would be more beneficial to have CMS involved in the Committee's deliberative process if diagnostics or treatments are developed for ME/CFS. This activity is not projected to take place during the two-year period that the new charter will be in effect, and (c) expand the Committee structure to add two new *ex-officio* positions for the Department of Veterans Affairs (VA) and the Department of Defense (DoD). Expanding the Committee structure to include these two government agencies will provide valuable information on services available to patients with ME/CFS and research being conducted on illnesses with similar symptoms to ME/CFS.

On September 5, 2016, the Secretary of Health and Human Services approved for the CFSAC charter with the proposed amendments to be renewed. The new charter has been made effective; the charter was filed with the appropriate Congressional committees and the Library of Congress on September 5, 2016. Renewal of the CFSAC charter provides authorization for the Committee to continue to operate until September 5, 2018. A copy of the Committee charter is available on the CFSAC website at <http://www.hhs.gov/advcomcfs>.

The PCFSN is a non-discretionary federal advisory committee. The PCFSN was established under Executive Order 13545, dated June 22, 2010. This authorizing directive was issued to amend the purpose, function, and name of the Council, which formerly operated as the President's Council on Physical Fitness and Sports (PCPFS). The scope of the Council was

changed to include nutrition to bring attention to the importance of good nutritional habits with regular physical activity for maintaining a healthy lifestyle. The PCFSN is the only federal advisory committee that is focused solely on the promotion of physical activity, fitness, sports, and nutrition. Since the PCFSN was established by Presidential directive, appropriate action had to be taken by the President or agency head to authorize continuation of the PCFSN. The President issued Executive Order 13708, dated September 30, 2015. Under the authority given in this directive, the Council can continue to operate until September 30, 2017.

No amendments were recommended for the PCFSN charter. The charter was approved by the Secretary of Health and Human Services on September 8, 2016, and it was filed with the appropriate Congressional committees and the Library of Congress on September 10, 2016. A copy of the Council charter is available on the PCFSN website at <http://fitness.gov>.

SACHRP is a discretionary federal advisory committee. SACHRP provides advice to the Secretary, through the Assistant Secretary for Health, on matters pertaining to the continuance and improvement of functions within the authority of the Department of Health and Human Services concerning protections for human subjects in research.

There was one amendment recommended and approved for the SACHRP charter. The charter stipulated that appointment of the Designated Federal Officer (DFO) was restricted to the Director of the Office for Human Research Protections. This restriction has been removed to allow for other senior level program and management OHRP staff to be considered for appointment as the DFO. On September 30, 2016, the Secretary of Health and Human Services approved for the SACHRP charter to be renewed. The new charter was filed with the

appropriate Congressional committees and the Library of Congress on October 1, 2016.

SACHRP is authorized to continue to operate until October 1, 2018. A copy of the charter is available on the Committee website at <http://www.hhs.gov/ohrp/sachrp/>.

The ACBTSA is a discretionary federal advisory committee. The Committee provides advice to the Secretary, through the Assistant Secretary for Health, on a range of policy issues related to the safety of blood, blood products, organs and tissues. For organs and blood stem cells, the Committee's work is limited to policy issues related to donor derived infectious disease complications of transplantation around the safety and availability of the blood supply and blood products.

There were two minor amendments recommended and approved for the ACBTSA charter. The charter has been amended to include the option for a Vice Chair and/or Co-Chairs to be appointed for the Committee leadership. The Committee structure has been expanded to include *ex-officio* representation from the Department of Veterans Affairs (VA). The VA has the largest conglomerate of hospitals in the United States. The agency has responsibility for the largest patient population that uses the largest quantity of blood and tissue products in the United States. Therefore, it was determined that involvement of the VA would be beneficial to the ACBTSA for ensuring that the Committee properly addresses current issues and concerns regarding blood and tissue safety and availability.

On October 5, 2016, the new charter for the ACBTSA was approved by the Secretary of Health and Human Services, and it was filed with the appropriate Congressional committees and the Library of Congress on October 9, 2016. ACBTSA is authorized to operate until October 9,

2018. A copy of the charter can be obtained on the ACBTSA website at

<http://www.hhs.gov/ash/bloodsafety>.

Copies of the charters for the designated committees also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is <http://facadatabase.gov/>.

Dated: October 20, 2016

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Acting Assistant Secretary for Health

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