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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2011-0011]

Public Health Service Guideline for Reducing Transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) through Solid Organ Transplantation

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

ACTION: Extension of the public comment period.

SUMMARY: On September 21, 2011, the Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), published a notice in the **Federal Register** requesting public comment on the draft "Public Health Service (PHS) Guideline for Reducing Transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) through Solid Organ Transplantation" (76 FR 58517). Written

and electronic comments were to be received on or before November 21, 2011. However, HHS/CDC has received requests for a 30 day extension of the comment period. In consideration of those requests, HHS/CDC is extending the comment period by 30 days to [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

CDC also published a supporting document for reference, the *Evidence Report*. The *Evidence Report* includes primary evidence, studies, and data tables that were used by the *Guideline* authors in developing the recommendations in the *Guideline*.

The draft *Guideline* is for use by organ procurement organizations (OPOs); transplant centers, including physicians, nurses, administrators, and clinical coordinators; laboratory personnel responsible for testing and storing donor and recipient specimens; and persons responsible for developing, implementing, and evaluating infection prevention and control programs for OPOs and transplant centers. This *Guideline* provides evidence-based recommendations for reducing unexpected transmission of HIV, HBV and HCV from deceased and living organ donors.

Dates: Written comments must be received on or before

[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER] .

Addresses: Written comments may be submitted electronically or by mail. To download an electronic version of the *Guideline*, go to <http://www.regulations.gov, Docket CDC-2011-0011>. You may submit written comments electronically at this website. Please follow directions at <http://www.regulations.gov> to submit comments.

You may also submit written comments to the following address: Office of Blood, Organ and Other Tissue Safety, Division of Healthcare Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, (CDC), Attn: *Public Health Service Guideline for Reducing Transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) through Solid Organ Transplantation*, Docket No. CDC-2011-0011, 1600 Clifton Rd, N.E., Mailstop A-07, Atlanta, Georgia, 30333. All written materials identified will be available for public inspection Monday through Friday, except for legal holidays, from 9:00 a.m. until 5:00 p.m., Eastern Standard Time, at 1600 Clifton Road, N.E., Atlanta, Georgia 30333. Please call ahead to (404) 639-4000 and ask for a representative from the Office of Blood, Organ and Other

Tissue Safety to schedule your visit. All relevant comments received will be posted publicly at this website without change, including any personal or proprietary information.

FOR FURTHER INFORMATION CONTACT: Debbie Seem, Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road N.E., Mailstop A-07, Atlanta, Georgia, 30329-4018; Telephone: (404) 639-4000.

SUPPLEMENTARY INFORMATION: Since 2008, HHS/CDC has collaborated with state and federal agencies, national partners, academicians, public and private health professionals, the transplant field, public health organizations, and other partners to revise and expand the 1994 *Guidelines for Preventing Transmission of Human Immunodeficiency Virus (HIV) through Transplantation of Human Tissue and Organs*. The 2011 draft *Guideline* updates the previous recommendations about HIV and also includes recommendations to reduce disease transmission of HBV and HCV, and addresses issues such as donor risk assessment, donor screening, HBV- and HCV-infected donors and transplantation, recipient informed consent, recipient screening, donor and recipient specimen collection and

storage, and tracking and reporting of HIV, HBV, and HCV. As with the 1994 *Guideline*, the recommendations address adult and pediatric donors who are living or deceased, as well as transplant candidates and recipients. In addition to summarizing current scientific knowledge about solid organ transplant safety, the draft 2011 *Guideline* also identifies important gaps in the literature where further research is needed.

HHS/CDC worked with the University of Pennsylvania's Health System Center for Evidence-based Practice (CEP) and sought input in each phase of the *Guideline's* development from subject matter experts in HIV and hepatitis through formation of a *Guideline* Expert Panel to develop the new *Guideline*. HHS/CDC also formed a *Guideline* Review Committee to provide feedback on the draft *Guideline*

recommendations. Members of the Review Committee included representation from public health, regulatory, transplant infectious disease and other stakeholders. This new Draft Guideline will not be a federal rule or regulation.

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