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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2014-0012]

Recommendations for Providers Counseling Male Patients and Parents Regarding Male Circumcision and the Prevention of HIV Infection, STIs, and other Health Outcomes

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

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), is seeking public comment on draft recommendations for health care providers who deliver information and counseling about elective male circumcision and the prevention of HIV and other adverse health outcomes to male patients and parents in the United States. The draft recommendations include information about the health

benefits and risks of elective male circumcision performed by health care providers.

DATES: Written comments must be received on or before [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments identified by Docket Number CDC-2014-0012 by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road N.E., Mailstop D-21, Atlanta, Georgia 30333. Attn: Male Circumcision Recommendations.

Instructions: All submissions received must include the agency name and docket number or RIN. All relevant comments received will be posted without change to <http://regulations.gov>, including any personal information provided. CDC will not consider or post any comments that

contain vulgar or offensive language, threats, personal accusations, and/or statements intended to promote commercial products or services, or images. Additionally, CDC will not post any pictures that are submitted. For access to the docket to read the recommendations, background document, or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Division of HIV/AIDS, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS D-21, Atlanta, Georgia 30329, phone: 404-639-5200. Email: circumcision@cdc.gov.

SUPPLEMENTARY INFORMATION: These recommendations are intended to assist health care providers in the United States who are counseling men and parents of male infants, children and adolescents in decision making about male circumcision. Such decision making is made in the context of not only health considerations, but also other social, cultural, ethical, and religious factors. Although data have been accumulating about infant male circumcision for many years, clinical trials conducted between 2005-2010

have demonstrated safety and significant efficacy of voluntary adult male circumcision performed by clinicians for reducing the risk of acquisition of human immunodeficiency virus (HIV) by a male during penile-vaginal sex ("heterosexual sex"). Three randomized clinical trials showed that adult male circumcision reduced HIV infection risk by 50-60% over time. These trials also found that adult circumcision reduced the risk of men acquiring two common sexually transmitted infections (STIs), herpes simplex virus type-2 (HSV-2) and types of human papilloma virus (HPV) that can cause penile and other anogenital cancers, by 30%. Since the release of these trial data, various organizations have updated their recommendations about adult male and infant male circumcision.

In addition to obtaining public comment on the draft Recommendations, CDC considers this document to be important information as defined by the Office of Management and Budget's (OMB) 2004 Information Quality Bulletin for Peer Review and, therefore, subject to peer review. CDC will share the summary of public comments with external experts who conduct a peer review of the evidence on this topic. Their review will include an evaluation of completeness, accuracy, interpretation, and

generalizability of the evidence to the United States and whether the evidence is sufficient to support the draft counseling recommendations.

After considering all public comment and the results of the peer review, CDC will publish a notice in the Federal Register announcing the final recommendations.

Dated: November 19, 2014.

Ron A. Otten,

Acting Deputy Associate Director for Science,

Centers for Disease Control and Prevention.

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