

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
HEALTH RESOURCES AND SERVICES ADMINISTRATION**



**Virtual Meeting of the CDC/HRSA Advisory Committee on
HIV, Viral Hepatitis and STD Prevention and Treatment
July 28, 2015**

Record of the Proceedings

TABLE OF CONTENTS

	<u>Page</u>
Minutes of the Meeting	
Opening Session.....	1
CHAC’s Formal Vote on a Draft Resolution.....	3
Update by the CHAC Data Workgroup	5
Review of Agenda Items for the November 2015 CHAC Meeting.....	6
Overview of CHAC’s Role and Responsibilities	6
New CHAC Business	7
Closing Session	8
Attachment 1: Participants’ Directory	10
Attachment 2: Glossary of Acronyms	12



**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
HEALTH RESOURCES AND SERVICES ADMINISTRATION**

**CDC/HRSA ADVISORY COMMITTEE ON
HIV, VIRAL HEPATITIS AND STD PREVENTION AND TREATMENT
July 28, 2015**

Minutes of the Virtual Meeting

The U.S. Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC) National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), and the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) convened a virtual meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC). The proceedings were held on July 28, 2015.

CHAC is chartered to advise the Secretary of HHS, Director of CDC, and Administrator of HRSA on objectives, strategies, policies and priorities for HIV, viral hepatitis and STD prevention and treatment efforts for the nation.

Information for the public to attend the virtual CHAC meeting via teleconference or webinar was published in the *Federal Register* in accordance with Federal Advisory Committee Act regulations. All sessions of the meeting were open to the public (*Attachment 1: Participants' Directory*).

Opening Session

Laura Cheever, MD, ScM
Associate Administrator
Health Resources and Services Administration
CHAC Designated Federal Officer, HRSA

Dr. Cheever conducted a roll call to determine the CHAC voting members, *ex-officio* members and liaison representatives who were in attendance. She announced that CHAC meetings are open to the public and all comments made during the proceedings are a matter of public record. She reminded the CHAC voting members of their responsibility to disclose any potential individual and/or institutional conflicts of interest for the public record and recuse themselves from voting or participating in these matters.

CONFLICT OF INTEREST DISCLOSURES	
CHAC Voting Member (Institution/Organization)	Potential Conflict of Interest
Bruce Agins, MD, MPH (New York State Department of Health)	No conflicts disclosed
Sanjeev Arora, MD, FACP (University of New Mexico Health Sciences Center)	Recipient of federal funding from HRSA and CDC; recipient of pharmaceutical research grants from AbbVie, Gilead Sciences, Merck and Roche for clinical trials of new hepatitis C virus (HCV) drug development
Guillermo Chacon (Latino Commission on AIDS)	Recipient of federal funding from CDC; member of Community Advisory Boards for Janssen Pharmaceuticals, Merck and ViiV Healthcare
Kathleen Clanon, MD (Alameda County, Oakland Medical Center)	No conflicts disclosed
Angelique Croasdale, MA (City of Hartford, Connecticut Department of Health and Human Services)	Recipient of federal funding from HRSA
Carlos del Rio, MD (Rollins School of Public Health Emory University)	Recipient of federal funding from CDC
Dawn Fukuda, ScM (Massachusetts Department of Public Health)	Recipient of federal funding from CDC and HRSA
Debra Hauser, MPH (Advocates for Youth)	Recipient of federal funding from CDC
Marjorie Hill, PhD (Consulting Services)	Recipient of federal funding from HRSA, including a 330 Ryan White HIV/AIDS Program (RWHAP) grant
Jennifer Kates, PhD (Kaiser Family Foundation)	No conflicts disclosed
Amy Leonard, MPH (Legacy Community Health Services)	Recipient of federal funding from CDC and HRSA, including an RWHAP grant

Dr. Cheever confirmed that the 16 voting members and *ex-officio* members in attendance constituted a quorum for CHAC to conduct its business on July 28, 2015. She called the proceedings to order at 3:06 p.m. and welcomed the participants to the virtual CHAC meeting.

Dr. Cheever explained that although the virtual meeting was published in the *Federal Register* and open to the public, a public comment session would not be held. She clarified that the additional meeting was being convened in between the regularly scheduled biannual meetings for the specific purpose of CHAC completing its May 2015 Business Session.

Kathleen Clanon, MD, CHAC Co-Chair

Medical Director

Alameda County Health Care Services Agency

Dawn Fukuda, ScM, CHAC Co-Chair

Director, Office of HIV/AIDS

Massachusetts Department of Public Health

Dr. Clanon and Ms. Fukuda also welcomed the participants to the virtual meeting. They particularly thanked the CHAC members and CDC/HRSA staff for taking time from their busy schedules to finalize CHAC's May 2015 Business Session. Ms. Fukuda concluded the opening session by reviewing the agenda items.

CHAC's Formal Vote on a Draft Resolution

Ms. Fukuda displayed a draft resolution for CHAC to consider and discuss before taking a formal vote. She explained that a small writing group drafted the resolution for CHAC to formally recognize the 25th anniversary of the Ryan White CARE Act.

Considering; that on August 18, 1990 the Ryan White CARE Act was enacted by Congress to address the alarming impact of the HIV/AIDS epidemic in the United States and Territories;

Considering; that the Ryan White CARE Act was named in memory of the courage and tenacity of a young man and his family's brave stand in the face of outrageous discrimination; and that Ryan White services continue to address racial, ethnic, sexual orientation, and class barriers that impede our desired goal;

Considering; that the Ryan White CARE Act developed, over the years, the most comprehensive model of care to provide treatment and other critical services to the most vulnerable and underserved populations impacted by the HIV/AIDS epidemic;
Considering; that the Ryan White CARE Act is a model that welcomes and affirms the active participation of people living with HIV in the policy, implementation and evaluation of program design and delivery;

Considering; the tremendous impact in the quality of life and life-saving treatment and support services, the Ryan White CARE Act has become a model of addressing an epidemic among low income and underserved communities throughout the nation and territories;

Considering; that recent Ryan White CARE Act data show that persons receiving care and services under this program have higher levels of retention in care and viral suppression than the general population of persons living with HIV;

Considering; the treatment model developed by the Ryan White CARE Act's programs underscoring and meeting the needs for training of providers to increase their delivery of these critical services to those most in need;

Resolve; CHAC recognizes each individual that contributed to developing this steadfast, groundbreaking, and comprehensive model of care in addressing the treatment and other critical services related to HIV in our communities across the United States and Territories;

Resolve; CHAC calls for proactive commemoration activities to begin in summer 2015 and continue throughout the fall at the Federal, State, and local levels to highlight the contributions and accomplishments of the Ryan White CARE Act.

CHAC also calls for all institutions, community-based organizations, and people living with HIV and AIDS to celebrate improvements in patient care and treatment through person-centered and holistic care to better address the evolving needs of those living with HIV and AIDS.

CHAC calls on all federal agencies and community partners to protect the effective services of the Ryan White CARE Act as a testament to catalyze health equity and as a model of responsiveness to the HIV and AIDS epidemic in a rapidly changing healthcare environment.

Co-Chair's call for a vote	Motion properly made by Mr. Guillermo Chacon for CHAC to formally approve the resolution Motion seconded by Ms. Angelique Croasdale
----------------------------	--

Outcome of vote	Motion unanimously passed by 11 CHAC voting members
Next steps	The Co-Chairs will include the resolution in a letter that will be sent to the HHS Secretary and the HRSA Acting Administrator. CHAC will be updated on any responses to the letter from federal officials.

Update by the CHAC Data Workgroup

Jennifer Kates, PhD

Vice President & Director, Global Health and HIV Policy
Kaiser Family Foundation
CHAC Member & Data Workgroup Chair

Dr. Kates covered the following topics in her update to CHAC on the workgroup's recent activities. CHAC took a formal vote during the December 2012 meeting and unanimously approved the establishment of the workgroup with the following charge: "assess emerging data that should directly inform the implementation of the Affordable Care Act (ACA), especially its relationship to prevention interventions and the delivery of care in Community Health Centers and clinics receiving RWHAP funds."

After the December 2012 CHAC meeting, the workgroup convened several conference calls with CDC and HRSA staff to identify key data issues related to ACA policies that need to be addressed. The workgroup presented regular updates of its activities during CHAC meetings in 2013-2014. The workgroup currently includes the following members.

- Chair: Jennifer Kates, PhD
- Members:
 - Bruce Agins, MD, MPH
 - Kathleen Clanon, MD
 - Angelique Croasdale, MA
 - Carlos del Rio, MD
 - Steven Johnson, MD
- CDC/HRSA Technical Assistance:
 - Stacy Cohen Gagne
 - Renee Stein, PhD
 - Richard Wolitski, PhD

Dr. Kates announced that the workgroup would convene its next conference call in August 2015 to identify next steps, explore future directions, and begin formulating recommendations to CDC

and HRSA on improving their data systems related to the role of ACA in the delivery of HIV prevention and care. She emphasized that the workgroup typically convenes two conference calls between CHAC meetings. She encouraged both new and existing CHAC members with an interest in joining the workgroup to e-mail her at jenniferk@kff.org.

Review of Agenda Items for the November 2015 CHAC Meeting

Ms. Fukuda noted that during the May 2015 Business Session, several members proposed items to place on the agenda for the November 2015 meeting. She asked CHAC to provide input on retaining or deleting these agenda items and suggest new topics that should be added.

CHAC AGREEMENT: AGENDA ITEMS FOR THE NOVEMBER 2015 MEETING	
Presenter(s)	Topic
Guest Speakers	Overview by health departments with low, medium and high HIV incidence that made presentations during the HIV testing trends meeting in Washington, DC
CDC and HRSA	Update on high-impact prevention activities
CHAC Membership	CHAC’s formal vote on a new draft resolution to support CDC’s request for a \$31 million increase in the Division of Viral Hepatitis budget. (CHAC will determine if this agenda item is still warranted based on whether CDC’s request was approved in the FY2016 budget.)
CHAC Membership	Formal vote on the draft resolution by the new Pre-Exposure Prophylaxis (PrEP) Workgroup
HRSA (Laura Cheever)	Overview of key findings from the two technical expert panels that HAB will convene on women and youth living with HIV
Dr. Sanjeev Arora	Update by the Hepatitis C Virus Workgroup

Overview of CHAC’s Role and Responsibilities

Antigone Dempsey, MEd
 Director, HAB Division of Policy and Data, HAB
 Health Resources and Services Administration

Ms. Dempsey described CHAC’s role and responsibilities as a brief orientation for the new members and a review for the existing members. The overview covered the following areas.

- CHAC's role to advise the HHS Secretary, CDC Director and HRSA Administrator as outlined in its formal charter.
- The scope and objectives of CHAC's advice to CDC and HRSA on their specific activities:
 - Prevention and control of HIV/AIDS, viral hepatitis and other STDs
 - Support of healthcare services to persons living with HIV/AIDS (PLWHA)
 - Education to health professionals and the public regarding HIV/AIDS, viral hepatitis and other STDs
 - Support of the agencies' response to prevention and health service delivery needs of affected communities and individuals living with or at risk for HIV, viral hepatitis and other STDs
- The CHAC membership and its diverse representation of PLWHA, African American, Hispanic, Asian/Pacific Islander, and gay/lesbian populations.
- Backgrounds of the CHAC membership, including community-based organizations, Community Health Centers, national organizations, healthcare providers, migrant health, the pharmaceutical industry, and federal, state and local public health.
- CHAC's recent issues and topic areas: enhancement of hepatitis prevention, treatment and care in the United States; integration of HIV prevention and care data systems; sexual health activities; RWHAP reauthorization; PrEP; and ACA implementation.
- CHAC's anticipated areas of focus in 2015-2016: youth, men who have sex with men, HCV, future directions of RWHAP, and the HIV epidemic in the South.
- Rules, regulations and other requirements to convene CHAC meetings (e.g., a quorum with CHAC voting members and *ex-officio* members, advance notice to inform the public of upcoming meetings, and the development of detailed meeting minutes).
- Differences between, definitions of, CHAC's process to make, and the agencies' consideration of formal CHAC resolutions and recommendations.
- Sample letter to the CDC Director and HRSA Administrator with CHAC's resolution on addressing barriers to HCV control.

Ms. Dempsey pointed out that guidance on making recommendations and resolutions was distributed to all CHAC members. She encouraged the members to use this resource to ensure that CHAC provides the agencies with the most clear and helpful advice.

New CHAC Business

Sanjeev Arora, MD, FACP

Professor, Department of Internal Medicine
 University of New Mexico Health Sciences Center
 CHAC Member & HCV Workgroup Chair

Dr. Arora proposed a new item for CHAC to consider placing on the agenda for the November 2015 meeting. CHAC has extensively discussed the lack of Medicaid coverage for HCV patients throughout the United States. Multiple clinicians are using the Gilead Sciences Patient Assistance Program to treat HCV patients at this time. Gilead drugs account for 90% of prescriptions for these patients because Medicaid consistently has denied nearly 50% of prescriptions.

As of July 1, 2015, the Gilead Patient Assistance Program is no longer available to Medicaid beneficiaries who are denied coverage. This new policy has resulted in a tremendous gap because clinicians have no source of funding to treat this subgroup of HCV patients. Most notably, Gilead drugs are the sole treatment option for patients with hepatitis C genotypes 2 and 3. A combination regimen by AbbVie is available, but this drug cannot be prescribed to patients with advanced liver disease, drug interactions or other contraindications.

Dr. Arora inquired about CHAC's role in providing guidance regarding the complete change in the landscape of HCV treatment in the United States. CHAC's advice would be a critical step in the development of a new policy to ensure that all HCV patients have access to treatment. He announced that the HCV Workgroup would convene two conference calls before the November 2015 CHAC meeting.

Mr. Chacon and Dr. Kates fully supported Dr. Arora's request to include this new item on the upcoming agenda. Dr. Clanon also serves on the HCV Workgroup. In preparation of the November 2015 CHAC meeting, she suggested that the workgroup consult with its federal colleagues to specify potential actions CHAC could take in this regard.

Ms. Fukuda concluded the discussion by confirming that time would be set aside during the November 2015 meeting for CHAC to discuss gaps in treatment of HCV patients between the Gilead Patient Assistance Program and Medicaid coverage. To support this agenda item, the workgroup would propose next steps for CHAC's consideration, discussion and formal action.

Closing Session

Ms. Fukuda reminded the participants that the next CHAC meeting would be HRSA-focused and convened as a webinar on November 4-5, 2015. With no further discussion or business brought before CHAC, she adjourned the virtual meeting at 3:44 p.m. on July 28, 2015.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

Date

Kathleen Clanon, MD, Co-Chair
CDC/HRSA Advisory Committee on HIV,
Viral Hepatitis and STD Prevention and
Treatment

Date

Dawn Fukuda, ScM, Co-Chair
CDC/HRSA Advisory Committee on HIV,
Viral Hepatitis and STD Prevention and
Treatment



Attachment 1: Participants' Directory

CHAC Members Present

Dr. Kathleen Clanon, Co-Chair
Ms. Dawn Fukuda, Co-Chair
Dr. Bruce Agins
Dr. Sanjeev Arora
Mr. Guillermo Chacon
Ms. Angelique Croasdale
Dr. Carlos del Rio
Ms. Debra Hauser
Dr. Marjorie Hill
Dr. Jennifer Kates
Ms. Amy Leonard

CHAC Members Absent

Dr. Virginia Caine
Dr. Camilla Graham
Dr. Steven Johnson
Mr. Michael Kaplan
Dr. Britt Rios-Ellis

CHAC Ex-Officio Members Present

Dr. Pradip Akolkar
U.S. Food and Drug Administration

Dr. Paul Gaist
Office of AIDS Research
National Institutes of Health

Dr. Iris Mabry-Hernandez
Agency for Healthcare Research and Quality

Ms. Lisa Neel
Indian Health Service

Dr. Richard Wild
(Alternate for Dr. Stephen Cha)
Centers for Medicare and Medicaid Services

CHAC Ex-Officio Members Absent

Dr. Stephen Cha
Centers for Medicare and Medicaid Services

Ms. Kaye Hayes
Office of HIV/AIDS and Infectious Disease Policy, U.S. Department of Health and Human Services

CHAC Liaison Representative Absent

Dr. Mildred Williamson
Presidential Advisory Council on HIV/AIDS

CHAC Designated Federal Officers

Dr. Laura Cheever
HRSA/HAB Associate Administrator

Dr. Hazel Dean
CDC/NCHHSTP Deputy Director

Federal Agency Representatives

Ms. Latuni (“Tonya”) Allen
Ms. Antigone Dempsey
Dr. Wayne Duffus
Ms. Shelley Gordon
Ms. Connie Jorstad
Ms. Theresa Jumento
Ms. Niki Keiser
CAPT Tracy Matthews

Dr. Eugene McCray
Ms. Margie Scott-Cseh
Ms. Kelley Weld
Mr. Erick Williams
Mr. Steven Young

Member of the Public

Ms. Stephanie Arnold Pang
National Coalition of STD Directors



Attachment 2: Glossary of Acronyms

ACA	Affordable Care Act
CDC	Centers for Disease Control and Prevention
CHAC	CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment
HAB	HIV/AIDS Bureau
HCV	Hepatitis C Virus
HHS	U.S. Department of Health and Human Services
HRSA	Health Resources and Services Administration
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
PLWHA	Persons Living with HIV/AIDS
PrEP	Pre-Exposure Prophylaxis
RWHAP	Ryan White HIV/AIDS Program