Advancing Telemedicine: A Federal Perspective
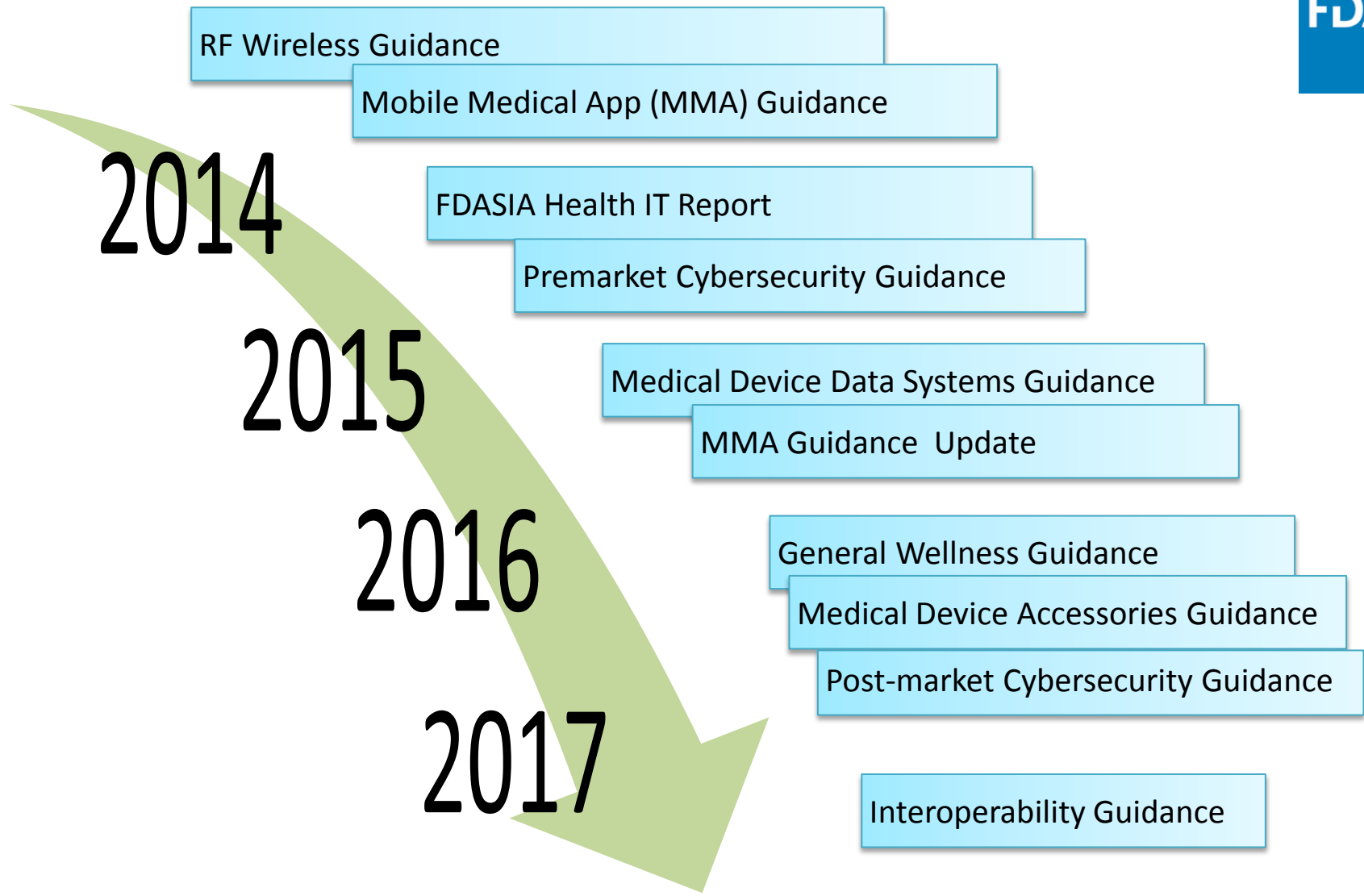
FDA and TeleHealth: An Evolving Landscape

Marisa L. Cruz, MD
Senior Medical Advisor
Center for Devices and Radiological Health, FDA

CDRH Objectives

- Enable "**patient-centered**" public health.

- Foster **trust in innovative technologies** as an enabler of a new health care paradigm.

- **Partner with customers** to be "digital-future ready".

FDA

2014

RF Wireless Guidance

Mobile Medical App (MMA) Guidance

FDASIA Health IT Report

Premarket Cybersecurity Guidance

2015

Medical Device Data Systems Guidance

MMA Guidance Update

2016

General Wellness Guidance

Medical Device Accessories Guidance

Post-market Cybersecurity Guidance

2017

Interoperability Guidance

FDA Approach to TeleHealth Products: The Upshot

- Tailored, risk-informed regulatory approach

- General wellness apps and MDDS products under enforcement discretion

- Focus on digital health/telehealth products whose functionality could pose a risk to patient safety if the product does not function as intended

Legislation and TeleHealth: Recent Developments

- 21st Century Cures Act codifies FDA approach by excluding MDDS and general wellness apps from definition of a medical device.

- MDUFA IV underscores importance of Digital Health by requiring the establishment of a Digital Health Unit, and requiring that the agency explore new premarket pathways and use of RWE in evaluating DH products.

Digital Health Innovation Action Plan

FDA

An Integrated Approach

Refine policies & provide guidance
- Issue guidance conforming to software provisions of the 21st Century Cures legislation
- Revise regulations for products that are not devices post 21st Century Cures
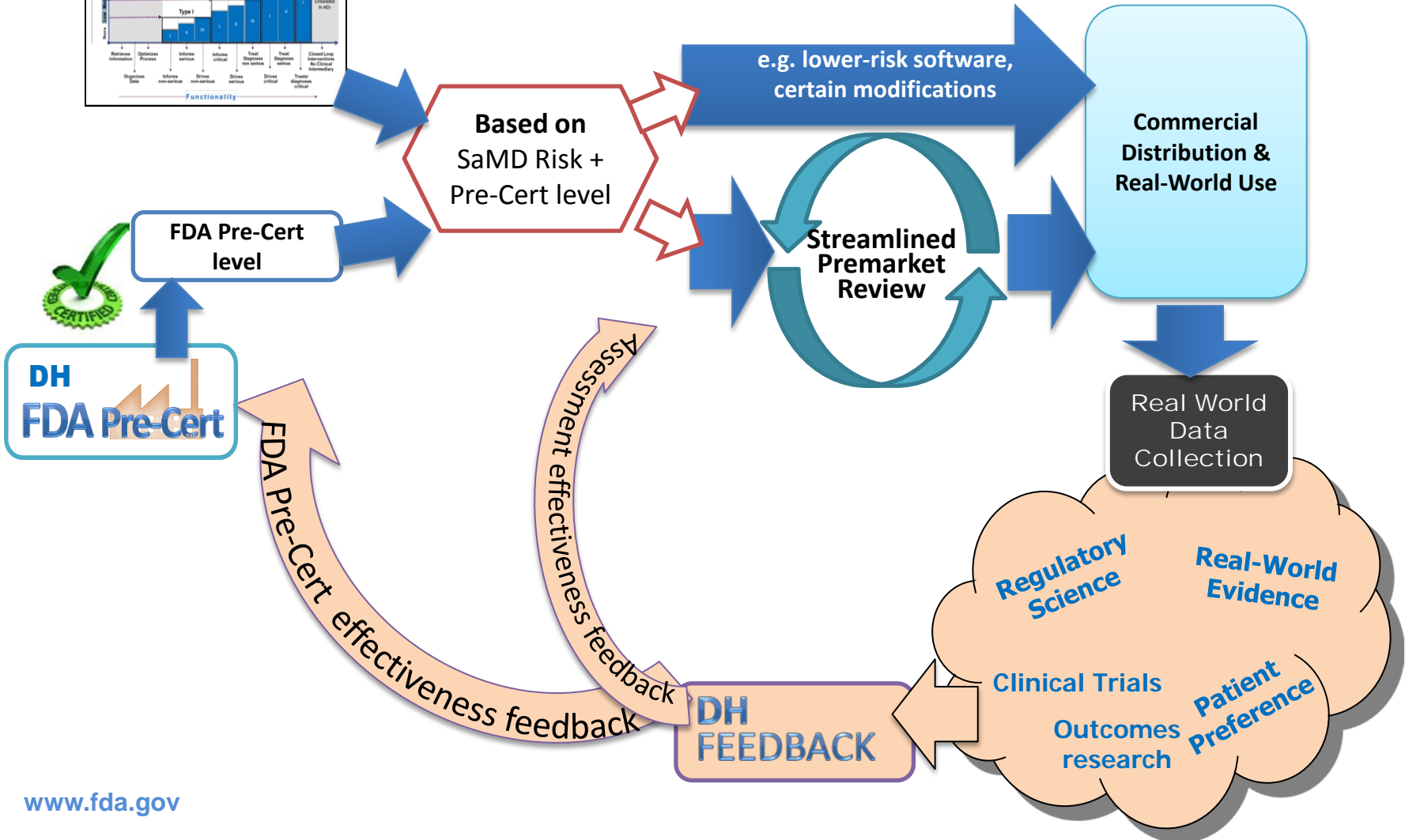
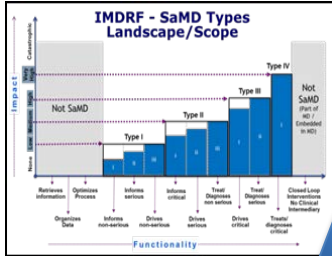**Explore new streamlined pathway for software**
- Launch an innovative pilot Precertification (Pre-Cert) program to build a new approach to digital health technology, working with our customers and leveraging internationally harmonized principles for software regulation

Building bench strength and expertise
- Build Digital Health unit with right technical expertise
- Launch digital health Entrepreneurs-in-Residence program for building the new paradigm

FDA Pre-Cert Pilot Program

Scorecard Framework

FDA

Excellence Principles

Product Quality

Proactive

Patient Safety

Clinically Responsible

Cyber Responsible

Common Validating Perspectives

Internal Processes	Objectives	Measures	Initiatives
Organization/Resource			
Customer Processes			
Learning and Growth	Objectives	Measures	Initiatives

How will we change and improve continuously toward the excellence principle?

Library of Key performance indicators and measures that demonstrate excellence

TeleHealth and Rural Communities

- FDA recognizes telehealth as an important tool for healthcare delivery in rural communities

- We aim to advance innovation and development in digital health while ensuring patient safety and effectiveness of telehealth devices

Be Part of the Discussion!

FDA

- Questions or comments about FDA regulation of telehealth and digital health products? Email digitalhealth@fda.hhs.gov

- Questions or comments about mobile medical apps? Email mobilemedicalapps@fda.hhs.gov

- Feedback on the Pre-Cert Pilot program? Stay tuned for webinar announcements and FAQs at our website: https://www.fda.gov/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/default.htm

- **End of Presentation**

VA Telehealth Update
at FDA Rural Health Symposium
Thurs Oct 26, 2017

John Peters, MS
Deputy Director
VHA Telehealth Services

- **Where We Started**
- **Where We are Today**
- **Where We are Going**
- **Anywhere to Anywhere**
- **Summary and Questions**

U.S. Department
of Veterans Affairs

Where We Started

1959 University of Nebraska Medical Center:

- **Two-Way Television**
- **Group Therapy**
  - Omaha VA
  - Lincoln VA
  - Grand Island VA Hospital

Image from Wittson, Cecil L.; Affleck, D. Craig; Johnson, Van Mental Hospitals, Vol 12(10), 1961, 22-23.

Where We Are Today

VHA TELEHEALTH: WHERE ARE TODAY

Where VA Telehealth Occurs

Home

- Home Telehealth Remote Monitoring
- VA Video Connect

Clinic

- Video Telehealth
  - Primary Care
  - Mental Health
- Store and Forward Telehealth

Hospital

- TeleICU
- TeleStroke

How VA Implements Telehealth

Facility

Telehealth encounters delivered to facility CBOCs and into the home

Regional

Telehealth Resource Hubs
- TeleDermatology
- TeleMental Health
- TelePrimary Care
- TeleRehabiitation
- TeleSleep

Map Legend
- V20 Hub
- SLC Hub
- Charleston Hub
- Pittsburgh Hub

National

Expert TeleConsultation
- National TeleMental Health Center
- TeleRadiology
- TeleGenomics

VHA Telehealth: 2017

- **>2.18 million** episodes of care
- **> 727,000 Veterans** served
    - 900 VA Sites of care
    - 88-94% Satisfaction (FY16-FY17)
    - >50 specialty areas
- **~12%** of Veterans received an element of their care through a Telehealth modality
- **<1%** of Veteran received care in their home or non-VA location
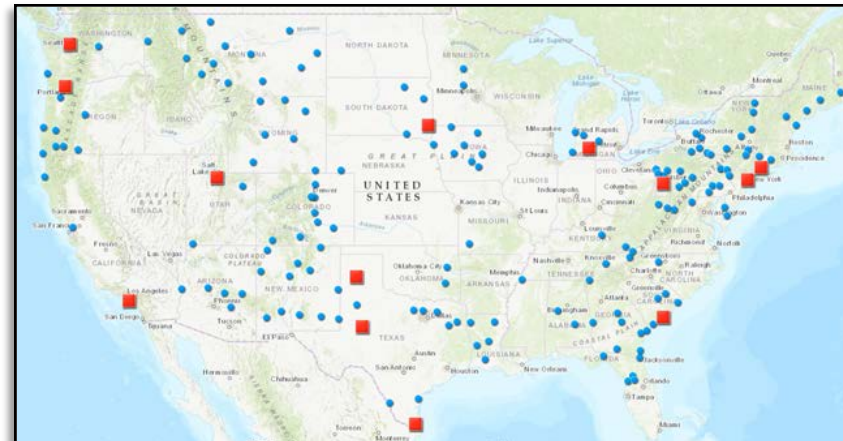
Telemental Health Hubs and Spokes
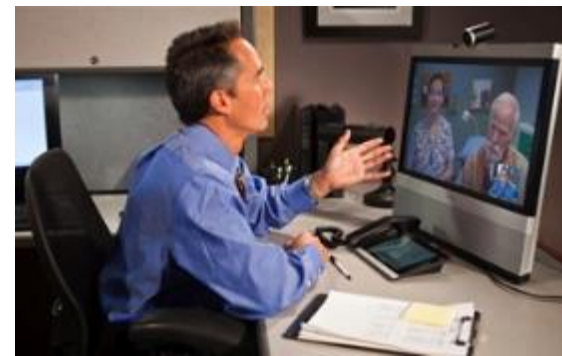

Tele-Primary Care Hubs and Spokes

Clinical Video Telehealth: TeleMental Health

Into the Home

Clinic Based

National Expert Consultation

Clinical Video Telehealth: Primary Care

Leverages TelePresenters and Exam Peripherals

- **Multidisciplinary team model**
- **In-person and video**

Store-and-Forward Telehealth:

- **TeleDermatology**
  - **About 107,000 FY17 Encounters**

- **TeleRetinal Imaging (TRI)**
  - **About 186,000 FY17 Encounters**
  - **Trained Imagers and TRI Equipment**

Remote Monitoring

- 145,000 Veterans in FY17
- Care and Case Management
- Devices, Software or Interactive Voice Response
- Chronic disease management, Independence

Chronic Disease Management

Independence/NIC

Home Telehealth

- TeleAddiction Services
- TeleAudiology
- TeleAmputation Care
- TeleBipolar Disorder
- TeleCardiology
- TeleChaplain
- TeleDental Care
- TeleDermatology
- TeleEpilepsy
- TeleGastrIntestinal/Hepatitis Care
- TeleGenomic Counseling
- TeleInfectious Disease
- TeleKinesiology
- TeleMOVE! Weight Management
- TeleNephrology
- TeleNeurology
- TeleNutrition

- TeleOccupational Therapy
- TelePain Management
- TelePathology
- TelePodiatry
- TelePolyTrauma Care
- TelePulmonology
- TeleRehabilitation
- TeleSchizophrenia
- TeleSpinal Cord Injury Care
- TeleSpirometry
- TeleSurgery (Pre & Post Care)
- TeleTransplant (Pre & Post Care)
- TeleSleep Medicine
- TeleWound Care
- Women's Telehealth

U.S. Department of Veterans Affairs

Where We Are Going

Facility Level: Accessibility

- Telehealth Integration (Home/Mobile)
- Float Providers
- Family Connect

Network Level: Capacity

- Interim Staffing (Resource hubs)
- Contact Centers/Veterans Crisis Line with LIPs

National Level: Quality

- Expert specialty consult centers
- Provider to Provider Consultation

Telehealth Integration

Providers will integrate video-into-the-home (or home communities) into routine operations, simply and flexibly scheduling ad hoc and future video appointments when beneficial for clinical efficiency, timeliness, capacity and/or accessibility.

Veterans will know the VA is reaching out to them and make their lives better.

Virtual Float Providers

Facility gap/float providers will substitute for short term, unexpected provider absences at remote clinics and/or assist with walk-in patients by delivering teleheatlh visits in open clinical spaces.

Veterans will know there is always a provider available to see them. Providers will know they have more time to spend with their complex, scheduled patients.

Family Connect

Veterans will have the option to invite or schedule caregivers and family members to attend telehealth and in-person appointments virtually, irrespective of the family member's/caregivers location.

Families and caregivers will feel connected to the organization. Veterans will know there is a community supporting in their healthcare goals.

Telehealth Interim Staffing

Core service provider vacancies at facilities will temporarily be filled within 30-days, 80% of the time, by leveraging Network or Regional clinical resource hub TeleProviders

Veterans will have consistent access to the core services irrespective of their location. PC and MH clinics will have the support they need to manage their panels.

Tele-Urgent Care

Veterans will have 24/7 access to licensed independent providers to assist with clinical advice, medical triage and basic urgent care treatment in order to enhance access and Veteran experience.

Veterans will know the VA is there for them, no matter the time of the day or night, irrespective of their location.

Telehealth National Expert Consultation

Veterans with select rare, complex or unique conditions will be treated with the assistance of national subject matter experts, when needed, by leveraging comprehensive telehealth services that are arranged and managed using efficient business processes.

Veterans know they will get the care they need, from the provider they need, no matter where they are in the country.

Immediate Access, Provider-to-Provider Telehealth Consultation

Provider-to-Provider specialty care consultation and advice, in key specialty service areas, are consistently and immediately available across the VHA enterprise to support Veterans at their Primary Care appointments.

Every provider, irrespective of their location, will know they have access to the resources of a national healthcare system to help with the care of their patients.

- VA will be issuing regulations authorizing our providers to care for our Veterans *Anywhere to Anywhere.*

- VA is also initiating the national rollout of VA Video Connect, a software application that will enable our providers to do telehealth *Anywhere to Anywhere*

What is VA Video Connect?

- **Video Conferencing Tool**
  - **Web based**
- Secure & Simple
- Connects Provider & Veteran
  - Any device
  - Any location

[Click here to Play VVC video](#)

VA Goal:

- Veterans will have greater choice and easy access to the benefits, care and services they earned

Anywhere to Anywhere Telehealth Initiative

- VA will leverage Telehealth technologies to enhance the **accessibility**, **capacity**, and **quality** of VA healthcare for Veterans, their families, and their caregivers.

Overview:
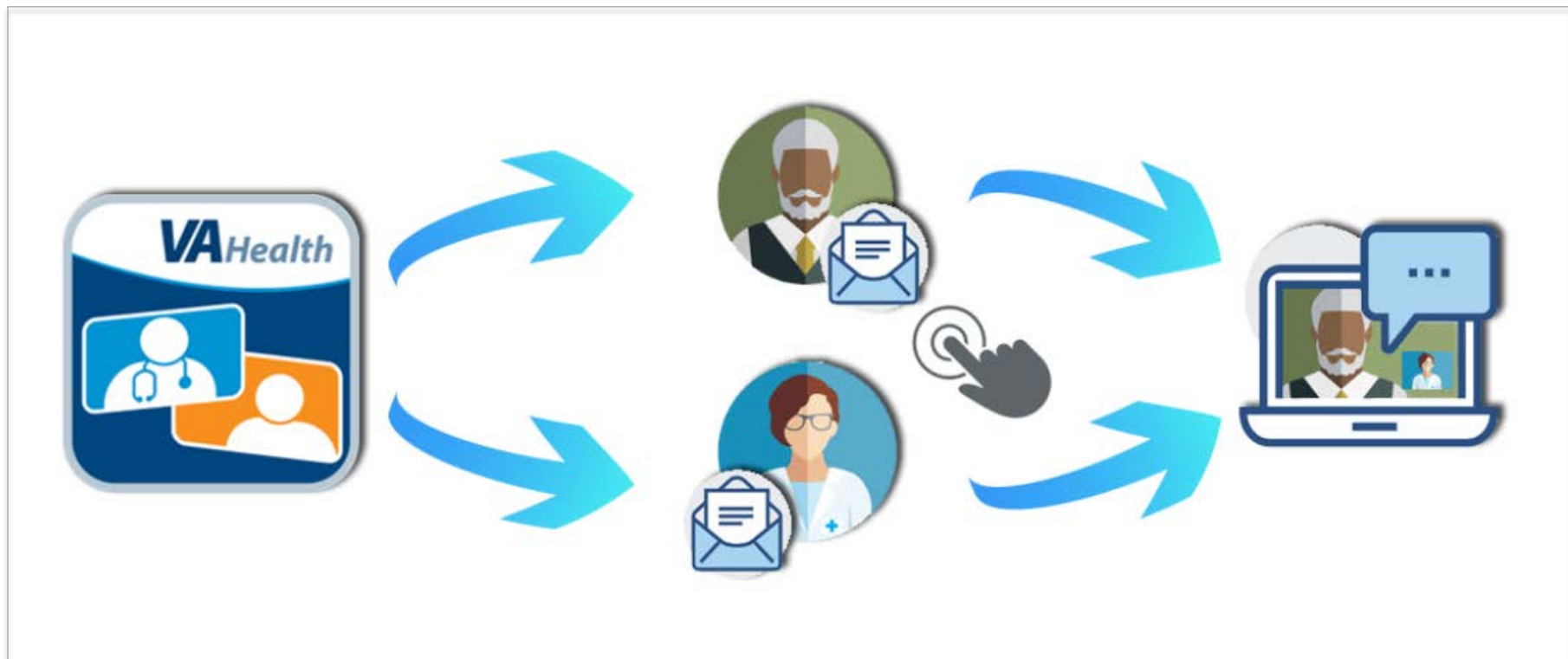
1. Schedule
VA Video Connect Visit

2. Open
Email & Click on link.

3. Join
Virtual Medical Room

Inside the Virtual Medical Room:

Tablet with Peripherals
(e.g., Primary Care, vital signs)

Tablet without
(Mental Health Services)

- Thermometer
- Pulse Oximetry
- Stethoscope
- Blood Pressure Cuff
- Weight Scale
- Close-up Exam Camera

Questions?

Contact John.Peters@va.gov
Department of VA
Office of Connected Care
VA Central Office – Washington DC
202-461-6946

- **End of Presentation**

FDA Rural Health Symposium
Office for the Advancement of Telehealth Programs

William L England, PhD, JD
Director

Federal Office of Rural Health Policy

October 26, 2017

U.S. Department of Health & Human Services

HRSA
Federal Office of Rural Health Policy

FORHP Programs 2017

Community-Based Division

- Rural Healthcare Outreach Services
- Network Planning & Network Development
- Small Healthcare Provider Quality Improvement
- Rural Health Opioid Program
- Care Coordination
- Benefits Counseling & Allied Health Workforce
- Delta Health Systems
- Black Lung Clinics Program
- Radiation Exposure & Screening Education

Policy and Research Division

- Rural Health Research Centers
- Rural Health Research Gateway
- Rural Health Information Hub
- Rural Policy Analysis
- Rapid Response Data Analysis
- Rural Health Value

Office for the Advancement of Telehealth

- Telehealth Network Grants
  - Evidence-Based (Emergency Departments)
  - School-Based
  - Rural Child Poverty
  - Substance Abuse
- Telehealth Resource Centers
- Telehealth Research Center
- Telehealth Centers of Excellence
- Flex Rural Veterans Health Access
- Licensure Portability

Hospital-State Division

- State Offices of Rural Health
- Medicare Rural Hospital Flexibility Grants
- Small Hospital Improvement Grants

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Office for the Advancement of Telehealth (OAT)

Mission: Promote the use of telehealth technologies for health care delivery, education, and health information services.

Definition: The use of electronic information and telecommunication technologies to support and promote long-distance clinical health care, patient and professional health-related education, public health and health administration. Technologies include video conferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications.

Activities: Administer nine grant programs, coordinate and collaborate on telehealth activities, monitor telehealth policy.

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OAT Grant Programs (FY2017) - $18.3 M

Program	Grants	Amount
Telehealth Network Grant Program	21	$6.2 M
Evidence-Based Telehealth Network Grant Program *	6	$2.1 M
Rural Child Poverty Network Grant Program *	4	$1.3 M
Substance Abuse Treatment Network Grant Program	3	$0.75 M
Rural Veterans Health Access Program	3	$0.90 M
Telehealth Resource Centers	14	$4.6 M
Licensure Portability Grant Program	2	$0.50 M
Telehealth-Focused Rural Health Research Center	1	$0.75 M
Telehealth Centers of Excellence	2	$1.2 M

* Ends in 2018

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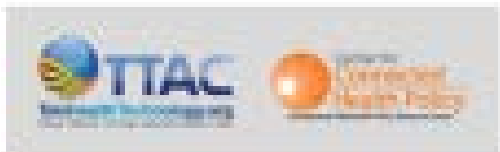
TelehealthResourceCenters.org

Telehealth Operations Module

Developed by: The Great Plains Telehealth Resource and Assistance Center under a HRSA Office for the Advancement of Telehealth grant

This module will address topics related to how a telemedicine service is established or developed and operated. In particular, it will focus on medical specialty consultation services provided via telemedicine where a medical specialist in any of a variety of fields from allergy and asthma to urology is involved with examining, diagnosing and treating a patient at another geographic location. Telemedicine is just one of several aspects of telehealth. If you are interested in home telehealth services, such as home monitoring, using telehealth technologies for distance learning or training, teleradiology, remote ICU services, telepharmacy, school based services or other types of services not listed here, you will need to consult other modules.

This module is intended to address the concerns and questions of organizations and providers who are interested in offering telemedicine services either within their own organization, to other medical care settings or even to individual patients. It is not intended to provide information to assist those who may be seeking health care via telemedicine.

This module is intended to provide assistance to those who are interested in establishing and operating telemedicine services for specialty consultations and direct patient care services, such as psychiatric evaluations, remote infectious disease evaluation and diagnosis, review and evaluation of pediatric echocardiograms, evaluation and treatment of skin conditions, genetic counseling, psychiatric medication management, to name but a few examples. The module will provide information about how to determine what kinds of services can be offered, how to obtain the support of a parent organization, how to organize the service within the parent organization, how to establish remote sites where patients are seen, how to execute the consultation process and how to maintain and improve the quality of that process.

View each section of this module by topic, at right »

Types of Telemedicine Specialty Consultation Services

Organization of Telemedicine Services

Getting Started

Staffing and Recruiting Specialists

Training

Facilities at the Provider Site

Facilities at the Patient Site

Credentialing and Licensing

Legal Issues (Privacy and Contracting for Services)

Creating Protocols

Pilot Testing

Introducing Telemedicine Services to the Community

Scheduling

Patient Preparation

After the Visit

Billing

Issues specific to Certain Types of Health Organizations

Evaluation

More Information

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Telehealth Legal and Regulatory Module
Developed by: The Center for Connected Health Policy

Telehealth raises a number of legal concerns, especially regarding cross-state practice and reimbursement. This module addresses many of the legal and regulatory issues affecting telehealth. This module is not intended to be a comprehensive analysis of the legal issues nor legal advice, but to highlight some of the more prominent legal issues that arise when using telemedicine technologies. For information related to reimbursement, please see the reimbursement module.

An attorney can help to determine whether or not a certain situation violates the law.

View each section of this module by topic, at right »

Cross-State Licensure

Privacy, Confidentiality and Security

Medical Malpractice and Liability

Credentialing and Privileging

Telehealth and Prescribing

Informed Consent Laws

Federal Communications Commission and Telehealth

Food and Drug Administration and State Regulations

Federal Trade Commission

Antitrust

The Electronic Health Record (EHR)

Federal Fraud and Abuse: Anti-Kickback Statute

Federal Fraud and Abuse: Stark Law

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Avera Telehealth Network Rural Chronic Care eConsult Project (South Dakota, Minnesota, and Iowa) - Telehealth Network Sites and Community-Based Rural Outreach, Quality, and Network Development Grantees

Evidence-Based Telehealth Network Grant Program

The EB TNGP is a competitive grant program to support implementation and evaluation of telehealth networks to deliver 24 hour Emergency Department consultation services via telehealth to rural providers without emergency care specialist.

- Project Period: 9/1/14 – 8/31/18
- 6 Awards up to $400,000/year

Rural Child Poverty Telehealth Network Grant Program

RCP-TNGP is demonstrating how telehealth can expand access to, coordinate and improve quality of health care for children in impoverished rural areas through integrating social and human service organizations.

Project Period: 9/1/15 – 8/31/18
4 Awards, up to $325,000/yr

Telehealth Focused Rural Health Research Center Cooperative Agreement

The purpose of this cooperative agreement is to increase the amount of publically available, high quality, impartial, clinically-informed and policy-relevant telehealth related research.

- Project Period: 9/1/15 – 8/31/19
- # of Awards: 1 recipient
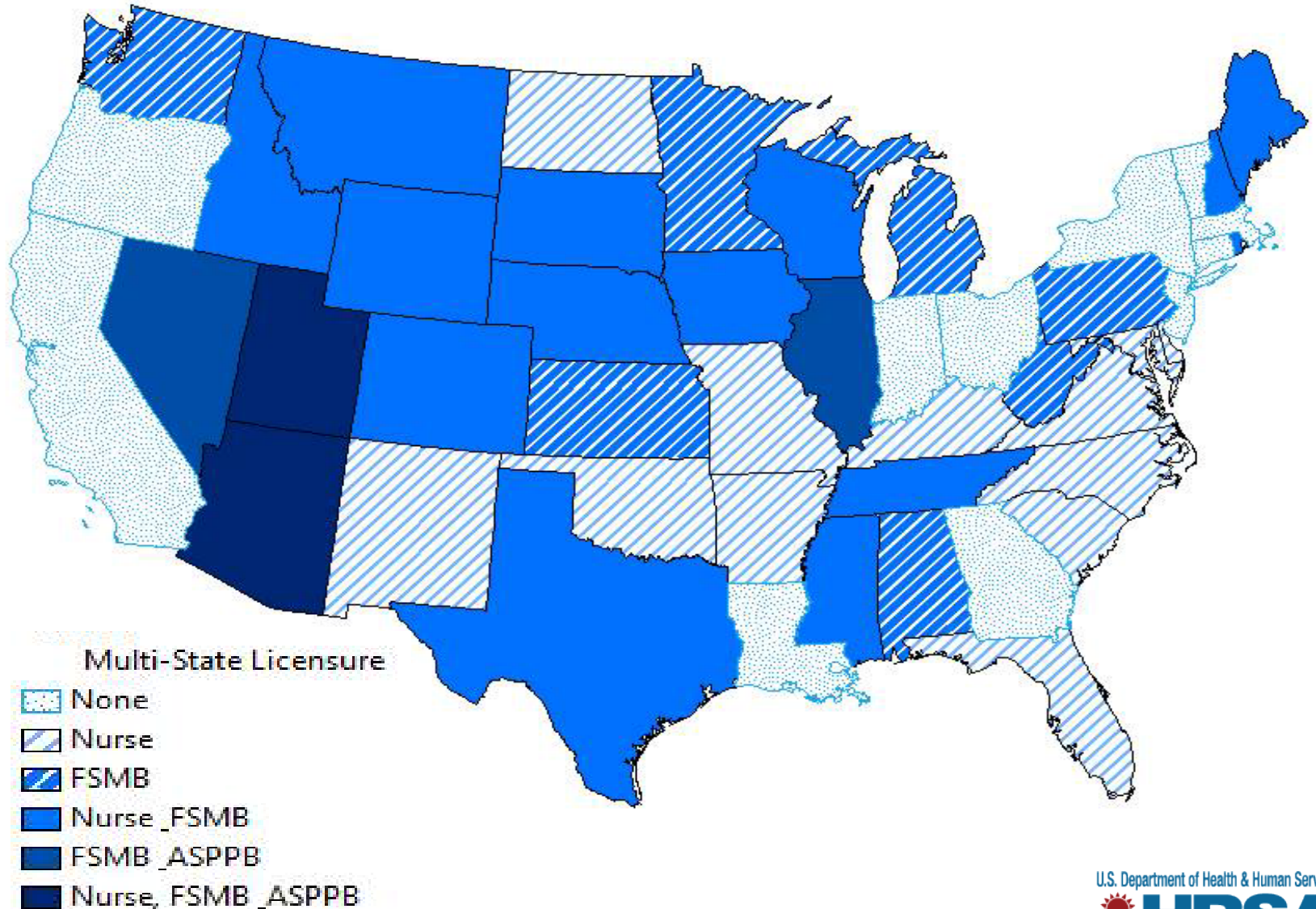- Amount: Up to $750,000/yr

Licensure Portability Grant Program

Supports state professional licensing boards to cooperate to develop and implement state policies to reduce statutory and regulatory barriers to telehealth.
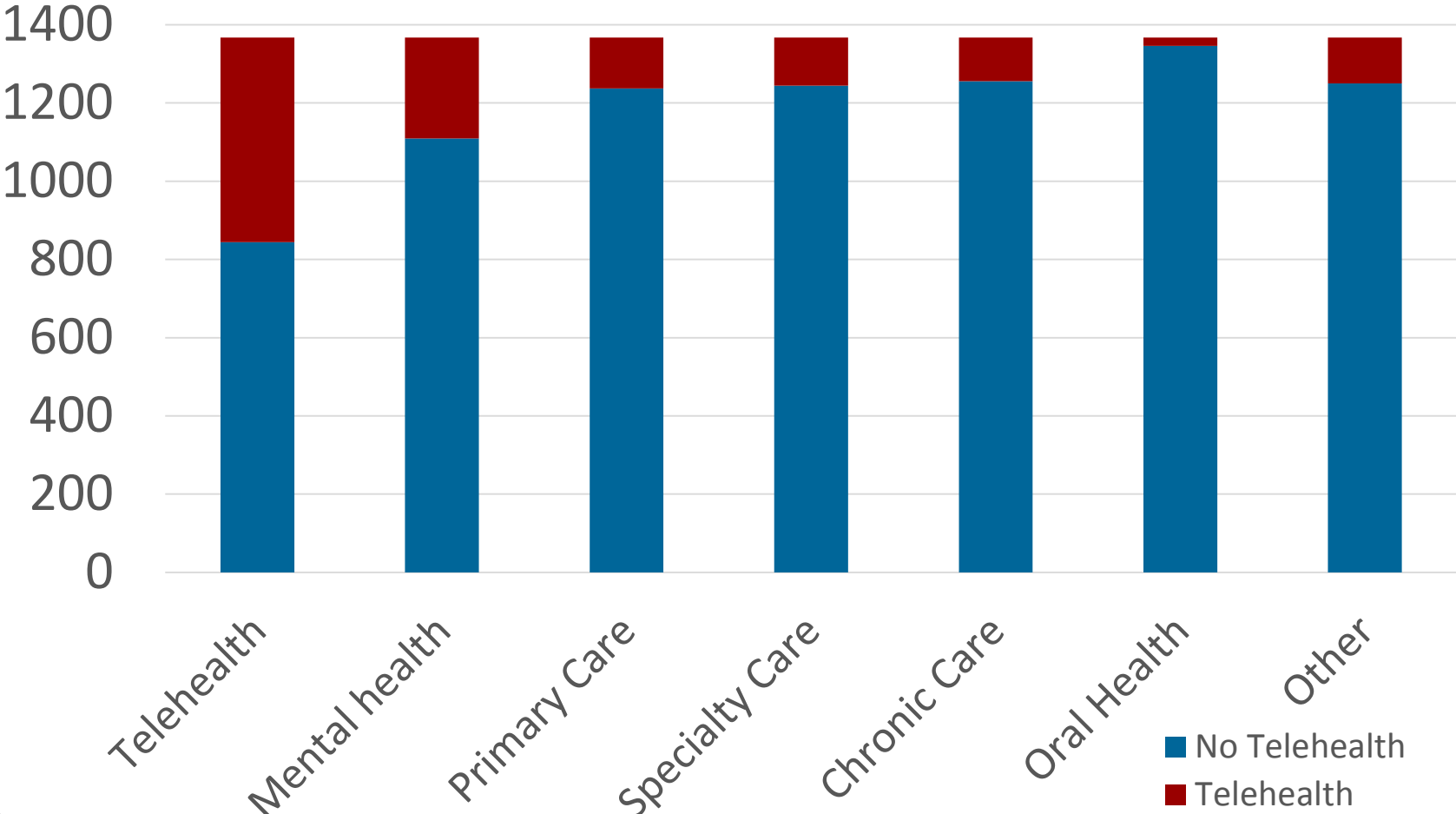
- Federation of State Medical Boards (FSMB)
  - Interstate Medical Licensure Compact (IMLC) (22 states)
- Association of State and Provincial Psychology Boards (ASPPB
  - Psychology Interjurisdictional Compact (PSYPACT) (3 states)
- Project Period 7/1/16 – 6/30/19, up to $250,000/yr.

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Multi-State Licensure Model Proliferation

Multi-State Licensure
- None
- Nurse
- FSMB
- Nurse _FSMB
- FSMB _ASPPB
- Nurse, FSMB _ASPPB

U.S. Department of Health & Human Services
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Telehealth Service in FQHCs 2016

National Rural Health Day

National Rural Health Day 2017 is Thursday, November 16!
National Rural Health Day is a call to action for all organizations that serve rural populations, State Offices of Rural Health, and rural communities to celebrate the power of rural! NRHD was created to increase awareness of rural health-related issues and challenges; as well as recognize those who are working to improve the health and wellbeing of the millions of people living in America's rural communities.

NRHD 2017 Celebrating the 30th Anniversary of the Federal Office of Rural Health Policy

You can help us achieve our goals of:
Partner Engagement
Resource Sharing
Future Collaboration

To get involved please email Michelle Daniels mdaniels@hrsa.gov
or Victoria Leach vleach@hrsa.gov

We Want You as a HRSA Grant Reviewer

Health Resources & Services Administration

HRSA

U.S. Department of Health and Human Services
Health Resources and Services Administration

Health Resources & Services Administration

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How to Apply   Manage Your Grant   Funded Projects   Grant Reviewers

HRSA Home > Grants > Grant Reviewers

Grant Reviewers

Share

HRSA uses health professions subject experts as peer reviewers to objectively evaluate a competitive group of grant applications against the published criteria in the HRSA Funding Opportunity Announcement (FOA). Reviewers are chosen based on their knowledge, education, experience and any criteria included in FOA that the applicants must respond to.

HRSA has specific interest in the following:

- Health professions training
- HIV/AIDS
- Maternal and child health
- Organ transplantation
- Primary care for underserved people
- Rural health

All professionals working in or knowledgeable about Health Care Services are invited to register in our Reviewer Recruitment Module database (RRM).

HRSA wishes to identify more qualified reviewers who have expertise in social, cultural or health care issues of rural, migrant or Native American populations. Please register in the RRM if you are interested in lending your expertise in any of these fields to our application review process.

HRSA uses an on-line grant review process called ARM, available 24/7 during the evaluation cycle to accommodate reviewer flexibility.

Each eligible application is read by at least 3 reviewers who then discuss their evaluation and initial scores with other reviewers on their panel. This process is completed for each application using the internet and telephone, a process that most often takes 3 days or less.

Each non-federal participant in the entire process receives an honorarium.

Apply Now to be a Grant Reviewer

If you have expertise in these areas and are interested in becoming a HRSA Grant Reviewer, register in the HRSA Reviewer Recruitment Module.

- **http://www.hrsa.gov/grants/reviewers/index.html**

U.S. Department of Health & Human Services
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Questions/Contact

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wengland@hrsa.gov

301-945-3987

- **End of Presentation**