#### The Multi-Purpose Agreement (MPA)

Establishing Trusted Interoperability and Patient Access to Data Throughout the Indian Health System in Support of Meaningful Use

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### Disclaimers

- This presentation, recordings, copies, or derived works are not representative of the actual agreement and should not be construed as such.
- The Presenter is not trained or authorized to provide legal advise.
- The Presenter cannot obligate the IHS in any way to the terms of the agreement, which is currently in draft.
- The purpose of the presentation is solely to provide a general overview of the Multi-Purpose Agreement (MPA) and as such only excerpts are represented here.
- All prospective Members should review the agreement in its entirety.

#### AGENDA

- Requested action
- Scope of the RPMS Network
- MPA drivers
- Overview of MPA and policies
- Next steps for MPA and policies
- Other Meaningful Use Stage 2 actions remaining
- Other questions about interoperability
- Open question and answer session

#### **Requested Action**

- <u>Impact</u> Without the necessary legal agreement and policy framework in place, IHS cannot complete the deployment of the centrally-managed enhancements to RPMS (PHR, Direct, HIE, and MPI), collectively called the RPMS Network, and sites will be unable to attest for MU in 2015.
- <u>Requested Action</u> Views and comments on the MPA due to CDR Mark Rives, Chief Information Officer (CIO), IHS at this email address: CIO@ihs.gov.

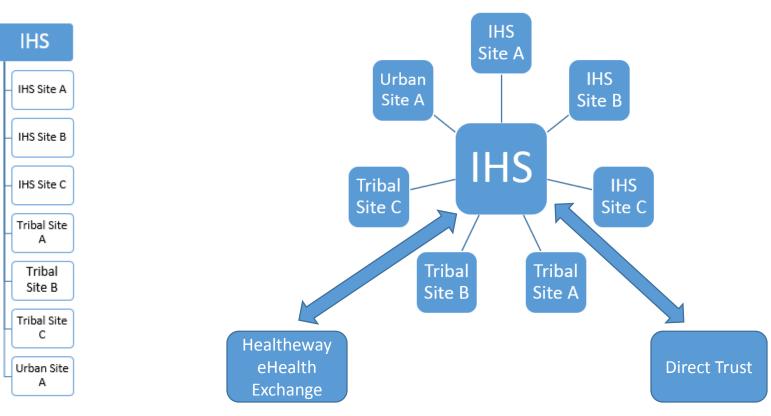
# History of IHS Data Exchange

#### Pre MU2

- IHS as data aggregator for reporting purposes.
- Bilateral relationship between IHS and tribes.

#### Post MU2

- IHS as data broker.
- Multilateral relationship between IHS and tribes.



## Scope of the RPMS Network

- RPMS Network:
  - Master Patient Index (MPI) provides a unique identifier for all patients registered across facilities that use the RPMS
  - Health Information Exchange (HIE [internal] / eHealth [external]) allows providers at one facility to access patient health summary documents from another location (I/T/U)and provides a gateway to the external, national Healtheway eHealth Exchange to support the exchange of information with other public and private health care partners
  - **Personal Health Record (PHR)** web-based portal that allows patients to access their personal health information
  - DIRECT Mail (DIRECT) enables directed, secure exchange of personal health information between providers and between patients and their health care teams using the Direct secure email protocol

#### **MPA Mission Drivers**

- Ensure the privacy, integrity, security of personal health information (PHI) and personally identifiable information, such that the Indian health system can effectively and safely carry out its mission while **ensuring our patients' trust in us**
- Bind T/U sites to the requirements of HealtheWay's DURSA for query-based exchange and DirectTrust for directed, secure email exchange
- Ensure compliance with HIPAA, Privacy Act, FISMA, and other laws, which are incorporated in the proposed IHS policies and MPA
- Avoid compromising our **mutual trust** vis-à-vis the RPMS Network, other tribes, our business associates, and other external exchange partners
- **Simplify the process** by combining multiple agreements into one **where possible** (e.g. Business Associate Agreement, Interconnection Security Agreement, and End User Agreement); reducing the number of executed agreements from 900 to 300
- Enable equitable information sharing and a level playing field between tribes, **honoring tribal sovereignty**, while establishing a federated trust framework
- Aligning processes with those of other HIEs, HISPs and federated exchanges at the national, state, or regional level
- Maintaining **integrity of the agreements** through one, consistent master MPA and a single, consistent signing document (the Joinder Agreement)

#### MPA Outline

#### Articles

- I. Definitions
- II. Recitals
- III. Member Obligations and Storage of Patients' PHI
- IV. Members Access to PHI
- V. Confidentiality and Security
- VI. Coordination of the Network
- VII. Interconnection Security Requirements
- VIII. HIPAA Business Associate Provisions Applicable to IHS
- IX. Liability and Indemnifications
- X. Addition of Subsequent Members
- XI. Term and Termination
- XII. Miscellaneous Provisions

Addendums - applicable Indian Health Service

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Policies and Procedures, Healtheway eHealth Exchange Data Use and Reciprocal Support Agreement (DURSA), etc.

Joinder Agreement – signing document

#### Article I: Definitions

- Includes legal and technical terms
- Read before trying to understand the terms in the MPA
- **Protected Health Information ("PHI")**. The term "Protected Health Information" and abbreviation "PHI" shall have the same meaning as the term "protected health information" at 45 CFR § 160.103, limited to the individually identifiable health information received by a Business Associate from or on behalf of a Covered Entity. This term shall include Electronic Protected Health Information. In this Agreement, PHI shall mean the written or electronic "Treatment" information stored by Members on the Network as more fully described in Section 3.01.
- Members. The term "Members" shall mean health programs operated by Indian tribes, tribal organizations and urban Indian organizations that are "Covered Entities" (as defined at 45 CFR § 160.102) and use the Network to access and share PHI under the terms of this Agreement. Members include IHS to the extent it accesses and uses PHI in accordance with Article 4.
- Network. The term "Network" shall mean, collectively, the IHS HIE, eHealth Exchange, RPMS DIRECT, IHS MPI, and IHS PHR.

#### Article II: Recitals

- Section 2.01 Purposes of Agreement.
  - Establish binding standards for Members to participate in accessing and sharing data over the Network
  - Facilitate PHI access and sharing for Treatment in a manner that complies with all applicable laws and regulations
  - Benefits in improved quality of patient care to be gained from the sharing of Individuals' PHI
  - Members desire to store patients' PHI on the Network, allowing other Members access to such patients PHI in order to provide better informed Treatment
- Section 2.02 Authority.: Transfer Act, 42 U.S.C. § 2001 et seq., Snyder Act, 25 U.S.C. § 13, Indian Health Care Improvement Act, 25 U.S.C. § 1601 et seq., (including but not limited to 25 U.S.C. § 1662, Automated Management Information System), Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. §§ 1320d-2 and 1320d-4, and 45 C.F.R. § 164.506(c)(2).
- Section 2.03 Consideration.
  - Members agree to share its patients' PHI, for Treatment purposes, in consideration of receiving access to the other Members' patient PHI, for Treatment purposes.
  - Members acknowledge that this consideration renders the Agreement legally binding among Members.

# Article III: Member Obligations and Storage of Patients' PHI

- Section 3.01 Storage of Patients' PHI.
  - IHS will create and maintain the Master Patient Index (MPI) . . . generates a unique patient identifier (ID) . . . enables the Health Information Exchange (HIE).
  - As soon as reasonably practicable . . . Members shall submit their patients' data, MPI demographic data, and patient encounter data for incorporation into the Network.
- Section 3.02 General Exchange Principles.
  - Processes in place to provide accurate and complete patient data
  - Prohibited uses:
    - Any use or disclosure not permitted by this Agreement;
    - Conducting comparisons of the performance of other Members; or
    - Any use that is prohibited by Federal law.
- Section 3.03 Members' Representation Regarding Legality of Access.
  - Members represent and warrant that it is authorized to allow Members access to PHI.
  - To the best of each Member's knowledge, storing the CCD on the IHS HIE does not violate any rights, including copyrights, of third parties.
  - Members shall obtain patient authorizations in accordance with applicable Federal or state laws.

# Article IV: Members Access to PHI

- Section 4.01 License.
- Section 4.02 Permissible Uses of the Network by Members.
  - Only for the permitted purposes described in this Agreement.
  - For Treatment purposes.
  - RPMS DIRECT to exchange PHI with the Indian Health System RPMS DIRECT participants, other trusted DIRECT partners, and patients and/or their personal representatives with registered accounts.
  - IHS PHR to provide patients with access to personal health records in accordance with policies governing access and use of the IHS PHR.
  - IHS HIE
    - To access eHealth exchange portal to view and share patient data for patient that have opted in with other eHealth Exchange partners.
    - Members shall be considered Participant Users under the Data Use and Reciprocal Support Agreement (DURSA) and shall comply with the terms and conditions.
  - Not use . . . for any purpose or in any manner that is prohibited by Federal law.
  - Not use . . . to aggregate data to compare the performance of other Members and/or Authorized Users.

## Article IV: Members Access to PHI (cont)

- Section 4.03 PHI Not Acquired from the Network. Does not apply to the use or disclosure of PHI that is in the possession of Members that was not acquired from the Network.
- Section 4.04 Access to PHI By Members' Authorized Users.
  - Members . . . determine the Authorized Users . . .
  - Tribal and Urban facilities not on the IHS D1 domain, access . . . is granted only after processing of a Help Desk ticket for each individual service.
  - Members . . . solely responsible for all acts and omissions of . . . its Authorized Users
  - Members attest:
    - (a) Authorized Users have received **training** regarding the confidentiality of PHI under the HIPAA Privacy and Security Rules and all other applicable Federal or state laws and agree to protect the PHI in compliance with the HIPAA Privacy and Security Rules, such laws and this Agreement;
    - (b) Authorized Users shall only access the Network as approved by its Member;
    - (c) Authorized Users have agreed to **protect all passwords**, or other means for accessing the Network, in a confidential and secure manner and to not release them to another person or entity;
    - (d) Authorized Users agree and understand that its failure to comply with the terms of this Agreement may
      result in the Authorized Users' exclusion from the Network and may constitute cause for disciplinary action by
      the Member;
    - (e) **Members restrict access** to the Network only to the Authorized Users that Members have identified pursuant to this Article.

# Article IV: Members Access to PHI (cont)

- Section 4.05 Treatment. . . . Members and its Authorized Users . . . solely responsible for all decisions and actions taken or not taken involving Treatment . . .
- Section 4.06 Acknowledgements Related to Access and PHI.
  - (a) . . . it is incumbent upon Members to verify the Individual's PHI with each Individual before the PHI is relied upon in treating or diagnosing . . .
  - (b) ... agree that IHS has not represented that its services have the ability to diagnose disease, prescribe Treatment, or perform any other tasks that constitute the practice of medicine or other health professions.
  - (c) IHS does not independently verify or review the PHI transmitted . . . for accuracy or completeness.
- Section 4.07 Inaccurate Data. All data to which access is made . . . is subject to change arising from numerous factors . . .

# Article IV: Members Access to PHI (cont)

- Section 4.08 / 4.09 Compliance with IHS Policies and Procedures.
  - Members agree to comply with IHS policies and procedures governing access and use of the Network.
  - . . . listed in Addendum A to this Agreement and may be found at the IHS website.
  - . . . acknowledge that these policies and procedures may be revised periodically and Addendum A may be revised unilaterally by IHS to reflect such changes.
  - Notification . . . will be made no later than 30 days before their effective date of implementation.
  - If Members object . . . it must so notify IHS and withdraw from this Agreement on or before the effective date of implementation.
  - If Members fail to object . . . they are deemed to have waived any objection.

# Article V: Confidentiality and Security

- Section 5.01 Confidentiality.
  - ... PHI obtained from the Network will be kept confidential pursuant to the HIPAA Privacy and Security Rules and all other applicable Federal or state laws, statutes and regulations, as well as Members' own rules and regulations ...
  - Any hard copy or electronic copy of PHI . . . will be placed in the Individual's medical record . . .
  - . . . other Members shall no longer have the right to control further downstream uses or disclosures of such PHI.
- Section 5.02 Privacy Act.
  - ... records ... maintained by IHS as part of the MPI are Federal records subject to the Privacy Act
  - Otherwise, records maintained by Members may be subject to the provisions of the Indian Self-Determination and Education Assistance Act (ISDEAA), including 25 U.S.C. § 450j(o) and deemed Federal records.
- Section 5.03 Confidentiality Enforcement by Members.
  - ... Members agree to report any breach of the confidentiality of the PHI ... as permitted by law.
  - Members agree to . . . appropriately disciplining persons . . . who violate the confidentiality of the PHI pursuant to each Member's respective confidentiality and disciplinary policies . . . may include, but not be limited to: warnings; suspensions; termination; or revocation of medical staff privileges.

# Article V: Confidentiality and Security (cont)

- Section 5.04 Access to Members' Organizational Confidential and Proprietary Information (Non-PHI).
  - IHS . . . will not provide . . . confidential and/or proprietary information to any other Member, person, or entity . . . Members shall be responsible for identifying whether information provided to IHS is Confidential and/or Proprietary Information.
- Section 5.05 Security.
  - Members shall implement security measures with respect to PHI obtained from the Network.
  - . . . shall comply with the HIPAA Privacy and Security Rules.
- Section 5.06 Malicious Software, Viruses and Other Threats.
  - . . . must provide "malware" (including without limitation malicious software or malware, viruses, worms and Trojan Horses) protection . . .
  - . . . ensure that the connection to and use of the Network will not introduce any program, routine, subroutine, or data.
  - . . . will not disrupt the proper operation of the Network or any part thereof 17 or any hardware or software used by IHS.

# Article VI: Coordination of the Network

- Section 6.01 IHS Role.
  - (a) IHS shall maintain and administer the Network . . . access to the PHI . . . granted to IHS . . . IHS may use contractor(s), subject to applicable Federal law.
  - (b) . . . acknowledge that other Members have access to the Network . . . [and] have agreed to comply with this Agreement . . . however, the actions of each Member are beyond the control of IHS . . . IHS does not assume any liability for or relating to any impairment of the privacy, security, confidentiality, integrity, availability, or restricted use of any information on the Network resulting from any Member's actions or failures to act.
- Section 6.02 Provision of Equipment, Software, and Training.
  - IHS . . . may provide the software . . . to access the Network, as well as training to use the Associated Software.
  - Members shall not modify, reverse engineer, decompile, disassemble, re-engineer or otherwise create or permit or assist others to

create the Associated Software or the Network, or to create any derivative works from the Associated Software or the Network. Members shall not modify the Associated Software or combine the Associated Software with any other software or services not provided or approved by IHS.

- Section 6.03 Disclaimer of Warranties.
- Section 6.04 Carrier Lines.
- Section 6.05 Use of Network Equipment.
- Section 6.06 Cooperation with IHS.

# Article VII: Interconnection Security Requirements

- Section 7.01 Description of Interconnection. The interconnection between the IHS and Members is a two-way path subject to Members' and IHS' firewall filtering . . .
- Section 7.02 Data Sensitivity . . . unclassified but Sensitive, up to and including "High" level of sensitivity as defined by National Institute of Standards and Technology (NIST) SP800-60 Volume 2, section D.14.4 "Health Care Delivery Services Information type".
- Section 7.03 User Community. . . Users who are authorized by Members and IHS may use this interconnection . . .
- Section 7.04 Information Exchange Security Technical Controls. Describes IHS and members required technical security controls (VPNs, firewalls, IDS, etc.)
- Section 7.05 Physical security controls at each end of the connection.
- Section 7.06 Logical access to information.
  - ... Access must be provided by a written approval process.
  - Access must be controlled by authentication and role-based methods to validate the users' access.
- Section 7.07 Trusted Behavior Expectations.
  - ... users with access to the Network have passed or will have passed a criminal background check and adhere to organizational policies and procedures ...
  - ... request access from IHS ... through the Information Technology Access Control (ITAC) system

# Article VII: Interconnection Security Requirements (cont)

- Section 7.08 Formal Security Policy. Policy documents that govern the protection of the data are the Indian Health Manual, Part 8, and the HHS Information Security Program Policy (see Addendum A).
- Section 7.09 Incident Reporting
- Section 7.10 Audit Trail Responsibilities.
- Section 7.11 Security Parameters.
- Section 7.12 Training and Awareness.
- Section 7.13 Security Documentation.
  - ... IHS systems have been certified and accredited and have appropriate supporting documents, including Risk Assessment Reports and System Security Plans.
  - Members may purchase commercial off-the-shelf (COTS) software and/or rely on custom software development for programming purposes. In such cases, Members must rely upon security documentation, certification and accreditation, if any, of such commercial vendors, consultants, or internal staff.

#### Article VIII: HIPAA Business Associate Provisions Applicable to IHS

- Describes IHS's role as a business associate
- Section 8.01 Limits on Use and Disclosure.
  - (a)IHS may use and disclose PHI to maintain the Network and make disclosures to Members for Treatment purposes. IHS agrees to not use or further disclose PHI other than as permitted or required by this Agreement or as required by law.
  - (b) IHS shall not use or disclose PHI for any fundraising or marketing purposes. Further, IHS will not make the following disclosures that are otherwise allowed to be made by Members under 45 C.F.R. § 164.512 unless compelled to do so by law or unless such a disclosure is specifically authorized or required by this Agreement:
    - (1) About victims of abuse, neglect, or domestic violence;
    - (2) For health oversight activities;
    - (3) For judicial and administrative proceedings;
    - (4) For law enforcement purposes;
    - (5) About decedents;
    - (6) For cadaveric organ, eye, or tissue donation purposes;
    - (7) To avert a serious threat to health or safety;
    - (8) For specialized government functions; or
    - (9) For workers' compensation purposes.
  - If IHS is requested to make a disclosure for one of the foregoing reasons, it shall forward such request to the Member so that it can coordinate and prepare a timely response. IHS shall make PHI available to the Member for the foregoing reasons if requested to do so in writing by the Member.

#### Article VIII: HIPAA Business Associate Provisions Applicable to IHS (Cont)

- Section 8.02 Safeguards.
- Section 8.03 Contractors.
- Section 8.04 Access to Records.
- Section 8.05 Reporting Use or Disclosures Not Authorized By this Agreement or Required by Law.
- Section 8.06 Notification of a Breach of Unsecured PHI.
- Section 8.07 Amendments to PHI.
- Section 8.08 Documentation and Provision of Disclosures.
- Section 8.09 Availability of Internal Practices, Books, Manuals, and Records.
- Section 8.10 Change or Revocation of Permission.
- Section 8.11 Notice of Privacy Practices.
- Section 8.12 Withdrawal. Notwithstanding any other provision, Members may withdraw from this Agreement in accordance with 45 C.F.R. § 164.314 if it determines that IHS, acting as a Business Associate, has violated a material term of this Agreement.

## Article IX: Liability and Indemnifications

- Section 9.01 Data. Except to the extent required by Federal law, IHS is not responsible for the content of any information transmitted or received through the Network.
- Section 9.02 No Indemnification. No indemnification for any loss, claim, damage or liability is intended or provided by any Member under this Agreement. Members shall be liable for any loss, claim, damage, or liability that Members incur as a result of its activities under this Agreement, except that the IHS, as an agency of the United States, assumes liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C.§ 2671 et seq. This Section shall survive the termination of this Agreement and the withdrawal of any Member.

# Article X: Addition of Subsequent Members

• Section 10.01 Addition of New Members. Members acknowledge that additional Members may be added to the Network upon execution of this Multi-Purpose Agreement.

## Article XI: Term and Termination

- Section 11.01 Term of the Agreement. The term of this Agreement shall begin on \_\_\_\_\_\_, 20\_\_\_\_\_ and shall last for a term of one (1) year. This Agreement shall automatically renew unless a Member has provided written notice of its intent to withdraw, with or without cause, at least thirty (30) days in advance of termination. The withdrawal of any Member shall not be considered a termination of the Agreement and the remaining Members shall continue to participate under the terms of the Agreement.
- Section 11.02 Use and Disclosure of PHI After Termination.
- Section 11.03 Use and Disclosure of PHI After Withdrawal.

## Article XII: Miscellaneous Provisions

- Section 12.01 Governing Law. The scope, performance, validity, enforcement, and all other aspects of this Agreement shall be governed by Federal law.
- Section 12.02 Multiple Counterparts.
- Section 12.03 Incorporation By Reference. All addenda attached to this Agreement are incorporated by reference and made a part of this Agreement as if those exhibits were set forth at length in the text of this Agreement.
- Section 12.04 Headings.
- Section 12.05 No Succession and Assignment.
- Section 12.06 No Third Party Rights.
- Section 12.07 Compliance with Laws.
- Section 12.08 Independent Entities.
- Section 12.09 Regulatory References.
- Section 12.10 Waiver of Breach.

- Section 12.11 Force Majeure.
- Section 12.12 Complete Understanding.

#### List of Indian Health Manual (IHM) RPMS Network Chapter Policies

- Incorporated by reference:
  - RPMS DIRECT Administrator Access Policy
  - RPMS DIRECT End User Access Policy
  - RPMS DIRECT Messaging Privacy Policy and Terms & Conditions
  - HIE Audit Policy
  - HIE Access Policy
  - HIE Privacy Terms & Conditions
  - MPI User Access Policy
  - MPI Administrator Access Policy
  - MPI Data Access Policy
  - PHR Audit Policy
  - PHR Terms & Conditions
  - PHR Patient Access Policy
- Data Use and Reciprocal Support Agreement (DURSA).
- IHS Policies: The General User Security Handbook/SOP 06-11a, IHS Technical and Managerial Handbook/SOP 06-11b and IHS

Manual Part 8, Chapter 12.http://www.ihs.gov/IHM/index.cfm?mod ule=dsp\_ihm\_pc\_p8c12. \*

\*Proposed new chapter in IHM, Part 8, Information Resources Management (IRM)

#### Impacted Stakeholders

- Hospital Executives (CEOs\*, EOs, Clinical Directors, etc.)
- Chief Information Officers (CIOs)
- Information System Security Officers (ISSOs)
- Health Information Management (HIM)
- Privacy Officers
- Legal Counsel
- Patients

\* Signatories.

## MPA and Policy Next Steps

- Communications and Outreach
  - Information Systems Advisory Committee (ISAC)
  - TSGAC and DSCTAC as requested
  - Dear Tribal Leader Letter
  - OIT hosted webinars for interested stakeholders:
    - Monday, March 30th, 1:00 2:00 PM MST (3:00 4:00 PM EST)
    - Wednesday, April 22nd, 1:00 2:00 PM MST (3:00 4:00 PM EST)
- Policy Actions
  - Complete security authorizations of RPMS Network systems
  - Complete agency clearance of policies and MPA
  - $\Box$  4/30/15 Due date for comments on MPA
  - Director approves policies and MPA
  - □ MPA executed by IHS with T/U sites via the Joinder Agreement
  - □ IHS Policies adopted by I/T/U sites
  - □ I/T/U begin national onboarding of patient data (CCDA repository, HIE, MPI, PHR, and Direct)

## MU2 Other Actions Remaining

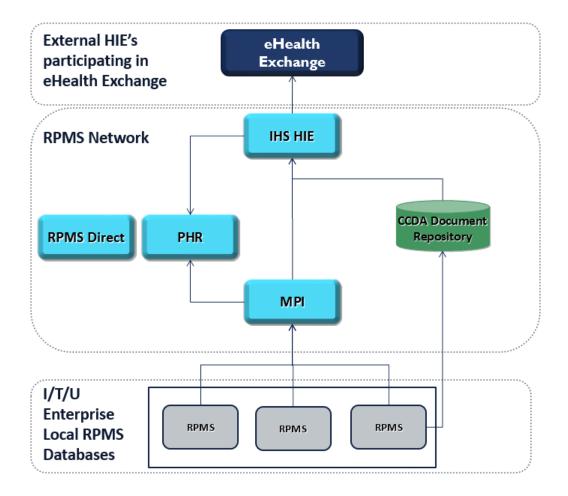
#### RPMS

- Complete CEHR deployment (over 80% complete)
- Modify performance measures
- Deploy CQM module
- Deploy syndromic surveillance changes
- RPMS Network
  - Direct Trust on-boarding
    - Direct Trust related EHNAC certification
  - Provision accounts for area and site level super users, systems administrators, HIM staff, and providers
  - Onboard clinical summary data from the sites into the RPMS Network (Albuquerque Data Center)
  - Outreach, identity vetting, and registration of patients
  - Operationalize the systems (staff help desks, respond to issues, improve on the system as budget allows, monitor performance and security, etc.)

Other Questions

- What about non-RPMS sites?
- What about connecting with state HIEs or regional HIEs?

#### Simplified Diagram of RPMS – eHealth Exchange Dataflow



# National eHealth Exchange Status

- **Complete** Development of IHS' HIE Connect components to integrate with the eHealth Exchange Connect Gateway.
- **Complete** Testing of the integration between IHS and eHealth Exchange.
- In Progress Updated DURSA.
- In Progress Agreements between IHS and Healtheway.
- **Planned** (within 90 days) First Interoperability Testing with an eHealth Exchange partner.
- **Planned** (within 120 days) Interoperable.

#### **Requested Action**

- Need input from all stakeholders on the content of the new MPA
- Share information about MPA, webinars, and comment period with your stakeholders
- Attend one of the following webinars:
  - Monday, March 30th, 1:00 2:00 PM MST (3:00 4:00 PM EST)
  - Wednesday, April 22nd, 1:00 2:00 PM MST (3:00 4:00 PM EST)
- 4/30/2015 Views and comments on the MPA due to CDR Mark Rives, Chief Information Officer (CIO), IHS at this email address: <u>CIO@ihs.gov</u>.