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Submitted electronically via: HIVOpenData@hhs.gov

Dr. Ronald Valdiserri, Deputy Assistant Secretary for Health, Infectious Diseases
Office of HIV/AIDS and Infectious Disease Policy (OHAIDP)
U.S. Department of Health and Human Services
Room 443-H, 200 Independence Ave. SW.
Washington, DC 20201.
Attention: HIV Open Data Project

Dear Dr. Valdiserri:

We are writing on behalf of the HIV Medicine Association (HIVMA) and the Ryan White Medical Providers Coalition (RWMPC) in response to the request for information regarding the creation of an online core dataset system for HIV programs by the Department of Health and Human Services (HHS). We are supportive of the initiative to create a core data system for HIV measures that will streamline data reporting requirements, reduce administrative burden and provide a comprehensive and uniform dataset for monitoring and evaluating HIV prevention and care delivery in the U.S.

The responses to the proposed questions that are noted below are a compilation of input received from HIVMA and RWMPC leaders working in HIV clinics and programs located in a diversity of geographic and practice settings. The detailed comments from several respondents are included as an attachment. We urge you to give special consideration as the process moves forward to the common themes identified below that emerged from the input that we received from Ryan White medical providers.

- Privacy protections must be a top priority. Patients and their providers must be reassured that the data will remain secure and confidential.
- The system and core measures must truly be standard across HHS programs and replace existing reporting requirements for clinical activities. The core measure reporting must not be a supplement or add on to existing reporting requirements.
- Programs should be able to access their own datasets to evaluate and monitor their programs and analyze the care provided and have the flexibility to generate program-specific data on a variety of variables.
- The core data system should have the flexibility to be operable and open to data reporting from private insurers. This is particularly important given that beginning in 2014 many people with HIV infection are likely to transition between public and private insurance coverage and/or rely on services supported by a mix of public and private payers.

1. In evaluating the feasibility of such a centralized data system, what specific steps would be critical to the design, deployment, operations, maintenance, and enhancement of such a system, particularly in light of addressing interoperability issues of existing data systems operated by DHHS OpDivs that support HIV prevention, treatment, or care services (e.g., Centers for Medicare and Medicaid Services, HRSA, Substance Abuse and Mental Health Services Administration, Indian Health Service, Centers for Disease Control and Prevention)?

Addressing issues related to data security and interoperability will be critical and should be the foundation of the initiative. The system must meet HIV-specific reporting requirements as well as be applicable to the adoption of other federal initiatives aiming to improve the delivery of care, including the Centers for Medicare and Medicaid Services Physician Quality Reporting System and the Electronic Health Records (EMR) "Meaningful Use" program.

Key issues to consider include:

- **The need to consider whether the data submission process will be a "push" or a "pull" system.** Under a "push" system -- programs upload the data to a central database but under a "pull system" a central site would be able to query grantee or participating institutions' databases for data with permission and approval as needed. Greater sophistication is required for a "pull" system so this may be limited in its applicability to many grantees, but a "pull" system is the direction that many healthcare systems are heading to support a "learning healthcare environment." An emphasis on compatibility with existing systems through interfaces or regular uploads is critical. Significant resources also should be dedicated to developing and maintaining these interfaces, and ensuring that they meet ONCHIT "certified EHR" standards so that their adoption and use will help qualify HIV providers to access and participate in the Medicaid and Medicare EHR meaningful use incentive programs.
- Monitoring and secure back-up systems would be required for a system relying on direct data entry into a national server to ensure servers are not overwhelmed. For many programs it is preferable to perform a periodic data upload from a local CAREWare (or other compatible) server, rather than direct data entry into the national server. Most programs with data management systems are tracking a large number of data elements that are directly entered by multiple users within the program (or local network) of which the dataset required by HRSA is only a small component. By allowing programs to upload on a regular, scheduled basis, it eliminates the need to enter data twice.
- **All Ryan White grantees regardless of their funding streams should use the same system and enter the same core data elements to avoid duplicate reporting and tracking by grantees who receive funding from multiple Parts.** Those datasets required for discrete purposes would have to be available on a pre-customized report (or download) basis.

2. What existing systems currently in use to monitor health grants offer the features desired and what are the strengths and challenges of (a) designing an entirely new online resource or (b) adopting an existing resource (e.g., HRSA's RSR or others)?

Given the evolving health care systems environment, the importance of "medical home" model metrics to quality comprehensive HIV/AIDS care,[i] and efforts to unify HIV/AIDS clinical quality and public health metrics across payers and providers[ii,iii] the proposed unified national HIV/AIDS data reporting tool must be aligned with other federal health information technology and clinical quality measurement and improvement programs and initiatives.[iv]

As emphasized in public comments on the Medicare and Medicaid electronic health record (EHR) "meaningful use" incentive programs, HIVMA urges HHS to target HIV medical providers to become meaningful users of certified HER technology *and to ensure availability of and access to certified EHR products that can be integrated or interfaced with existing federal grantee data collection and reporting needs*.

For Ryan White-funded HIV/AIDS medical providers, the tools that are already used for grant administration (such as HRSA's Ryan White HIV/AIDS Program Services Report and Electronic Hand Book) are a logical place to start. However, under this approach it will be important for HHS to work with commercial vendors to develop standardized EHR modules that are compatible with existing reporting tools, optimized to meet HIV/ AIDS reporting requirements across federal agencies, and certified to Meaningful Use standards.

If the project goes in the direction of building a new online resource where data are to be uploaded, one proposed way to decrease the burden on participating institutions would be to work with large commercial vendors of certified electronic medical record (EMR) products so that the forms that are in their systems to be used in routine care can populate the data that will later be extracted for national reporting. Working with these vendors to create standard queries and an interface to upload results to the new online resource will greatly decrease the time burden on HIV programs and allow increased time to be devoted to the provision of other services.

3. What are the greatest challenges encountered in reporting data (describe your reporting obligations, if applicable) and what specific solutions have DHHS grantees implemented to streamline divergent, non-interoperable reporting systems?

The greatest challenges arise from the required use of multiple data systems to enable reporting to an often diverse set of funders. The heterogeneity of data elements by funder is currently a major issue for programs receiving funding from multiple funders. In order to compile these data, partners are asked to report their data in a specific format. Much time is spent "cleaning" the data, making sure that all identifiers are accurate, that duplications are removed and that the data are valid. Interoperable systems with well-defined data capture forms and queries would produce standardized data sets and facilitate the combination of data from divergent sources.

Experiences with state based (Part B) central HIV CAREWare systems which require all grantees to provide direct data entry also offer lessons on pitfalls to be avoided with centralized data collection systems. Grantees have found it cumbersome when required to ask "permission" to download their own data back into their own servers if they want to use it. For this reason direct data entry into any centralized (state or federal-based) server should be designed to ensure efficiency and should include back-up systems to ensure that servers are not overwhelmed. In some cases, providers have found web-based state servers inadequate to accept simultaneous data inputs by multiple providers, resulting in slow connection speeds particularly in rural areas.

4. What data would prove most useful for different stakeholders to receive from such a centralized system?

The ability at the national level to aggregate data for use in evaluating access to prevention and care is critical to inform policy-making and funding decisions. However, it also is critical for programs to be able to retrieve program-specific data to support program evaluation and analysis. Program specific data is currently not available through the HIV/AIDS Bureau's RSR system and is a source of frustration for grantees that devote significant resources to reporting data that they are unable to use to inform their own program management and evaluation.

Specific data and reports that it would be helpful for grantees to receive include:

- A general view that would allow stakeholders to learn about the health utilization of patients at other facilities so they have a more complete picture of their care. In addition, linking the dataset to other national resources, such as the national death index, could provide important information on patients lost to follow up.
- Business analytics could be used to evaluate cost of care and such analyses could point to opportunities for cost saving and enhanced organizational efficiencies.
- Other specific data elements that that would be helpful to track include routine HIV measures, such as medical visits, HIV serology, HIV RNA, CD4, drug resistance, medications; concomitant conditions, such as viral hepatitis, depression and substance use, primary care data, such as other illnesses, cardiovascular risks, preventive screening, obesity, smoking, and linkage and retention in care. Site-specific customized variables also would be helpful to monitor indicators that may be unique to a program's patient population.

5. What costs, benefits, and risks need to be given careful consideration in development of such a resource? What are the estimated costs and return on investment of each component?

Potential benefits of the system include a more efficient use of limited clinical and research workforce resources, improved evaluation of federally funded HIV-related services across federal agencies and the ability to collect indicators for HIV-infected patients with public and private payer sources (or a combination of the two) to help with universal management of a program's patient population.

The return on investment should take into account the ability to more efficiently target resources to where they are urgently needed. In calculating costs, the costs and risks related to privacy protection must be considered. In addition, financial costs should fully reflect the cost of data reporting by taking into account time devoted to reporting by clinical and research staff. If this system does not fully replace current grantee data reporting requirements then the total costs of all grantee data reporting must be considered.

6. What technological resources and expertise would be needed to design, deploy, operate, maintain, and enhance such a system and what extant models exist for achieving the goal of a secure electronic resource capable of achieving the benefits noted above?

This would very much depend on the technological path chosen. We recommend that the process include partnering with vendors of certified EMR products that are tailored for HIV/AIDS practices to facilitate and make recommendations both for data collection and data reporting. Through consultation with stakeholders and certified EMR vendors, the resulting data quality will be greatly enhanced and stakeholders will benefit from more streamlined data collection and reporting. At the same time, stakeholders without EMRs will have an additional reason to move towards adoption of a certified EMR as their reporting will be greatly simplified, and they will gain access to federal incentive payments to support startup costs and meet "meaningful use" requirements.

7. What system architecture do you recommend for the project, particularly considering the government's desire to keep the project simple and streamlined (i.e. using as few different software packages and tools as possible)? What architecture, expertise, and other components are indispensable to the success of the design, deployment, operations, maintenance, and enhancement of such a system?

The goal should be for all Ryan White Parts as well as other HHS HIV/AIDS service provider grantees to use the same reporting system and enter the same standardized data elements. Grantees should only be required to upload data into one system – they should no longer have to submit individual reports to a state Part B server or a Part A server in addition to the federal-level reporting.

Grantees currently face challenges with their EMR vendors and getting full access to their data sets, so they can perform their own analysis rather than having a third-party interpret the data. For this reason, grantees must be able to control data integrity and validation processes.

Facilitating ease of reporting is of crucial importance, as well as building upon or interfacing with existing EHR systems and capacities. If a new unified web-based system is to be created, it should have the capability for HIV service providers to easily and quickly upload data from existing systems where possible. Such a system should also enable sites to easily access their own datasets for quality improvement, clinical practice management and research purposes.

Datasets that are required for discrete purposes would have to be available on a pre-customized report (or download) basis. The encryption system must be standardized and fully tested to ensure that data can be securely, quickly and easily entered – or, preferably, uploaded. In addition, data reports must be

useful to grantees and available on a timely basis, including a user-friendly system for grantees to request customized program-level reports.

The simplest solution may be working with designated certified EMR vendors to facilitate data collection and reporting, making it seamless for stakeholders to subsequently upload their information. This will require identification of key certified EMR vendor systems that are tailored (or can be tailored) to the needs of HIV clinical practices and/or that already hold a significant market share in the HIV community.

Overall, a national system needs to be designed so that users can seamlessly input data (preferably by uploading existing data sets) and be guaranteed that cross-platform compatibility is ensured on a timely basis. Data collected should be available on both a raw and 'processed' basis in the form of customizable reports that are useful not only to HRSA but to grantees as well.

8. What would a phased implementation plan consist of? If a modular or phased approach is recommended, what is a realistic timeframe for the completion of the project?

As previously referenced, the proposed initiative should strive to simplify data reporting by combining reporting requirements from as many agencies as possible. This will require standardization across agencies regarding data elements and how they are collected. The first step should involve getting all the agencies under HHS to agree on common data requirements that would fit all their needs while not imposing a hardship on the grantees.

Implementation should be overseen by representatives from all of the grant administration or health IT offices of the participating agencies and a representative of the soon-to-be-appointed Chief Medical Officer of the Office of Consumer eHealth that is being established in the ONCHIT.[v] In addition, we would include participation or consultation with large private plans to support collaboration and reporting across sectors. Thorough testing by grantees should be conducted at each implementation and reporting step to ensure performance as use increases.

9. What additional information not specifically addressed elsewhere in this RFI that would be important for the government to bear in mind in developing such a system?

One of the main drivers behind the development of a central data reporting system must be to facilitate data reporting by reducing duplicative reporting and developing standardized data elements across funders. A new data reporting system will be of limited value if the process does not include a refined minimum data set and collaboration with commercial vendors to streamline both data collection and data reporting. Financial incentives for clinics reporting data directly from electronic systems also should be considered to move the field towards more standardized data collection and reporting practices.

Thank you for the opportunity to share our views on this important undertaking, and for all your work to ensure successful implementation and evaluation of the National HIV/AIDS Strategy. Please consider the HIVMA and the RWMPC as resources as this initiative moves forward. We may be reached through the HIVMA executive director Andrea Weddle at (703) 299-0915 or aweddle@hivma.org or the RWMPC

convener Jenny Collier at (202) 543-0353 or jennycollierjd@yahoo.com.

Sincerely,

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Chair, HIV Medicine Association

James L. Raper, DSN, CRNP, JD, FAANP, FAAN
Co-chair, Ryan White Medical Providers Coalition

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[i] Gallant et al, "Essential Components of Effective HIV Care: A Policy Paper of the HIV Medicine Association of the Infectious Diseases Society of America and the Ryan White Medical Providers Coalition," Clin Infect Dis. (2011) doi: 10.1093/cid/cir689 First published online: October 20, 2011. Accessed online on 5/21/2012.

[ii] Horberg et al, "Development of National and Multiagency HIV Care Quality Measures," Clin Infect Dis. (September 15, 2010) 51 (6): 732-738. doi: 10.1086/655893.

[iii] National Academy of Sciences, Institute of Medicine, "Monitoring HIV Care in the United States: Indicators and Data Systems," report brief, p. 3, accessed online 5/21/12 at http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=3519..

[iv] Including the Medicare and Medicaid Electronic Health Record Meaningful Use Incentive Programs and the Physician Quality Reporting System and NCQA's Patient-Centered Medical Home Recognition Program (http://www.ncqa.org/tabid/631/Default.aspx).

[v] Reported May 16, 2012 at http://www.healthit.gov/buzz-blog/from-the-onc-desk/positioning-onc-continued-success/ (accessed online 5/21/2012).