



June 10, 2014

Leroy Richardson  
Chief, Information Collection Review Office  
Centers for Disease Control and Prevention  
1600 Clifton Road, MS D-74  
Atlanta GA, 30333

**RE: [FR Doc. 2014-08170] Proposed Data Collections Submitted for Public Comment and Recommendations (CDC Diabetes Prevention Recognition Program)**

The Healthcare Leadership Council (HLC) is pleased to respond to the Centers for Disease Control and Prevention (CDC)'s request for public comment on proposed data collections for the CDC Diabetes Prevention Recognition Program (DPRP). HLC's comment letter addresses alternate data reporting suggestions to ensure wide participation among all organizations seeking recognition under DPRP.

HLC, a coalition of chief executives from all disciplines within American healthcare, is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century system. HLC members advocate measures to increase the quality and cost-effectiveness of American healthcare by emphasizing wellness and prevention, care coordination, and the use of evidence-based medicine, while utilizing consumer choice and competition to elevate value.

HLC members have long supported prevention and wellness activities that will help patients detect and mitigate risk factors for chronic diseases such as diabetes. HLC co-chaired the Medicare Diabetes Screening Project, which, among other activities, recently sought to enroll Atlanta-area seniors in the National Diabetes Prevention Program (NDPP). Additionally, HLC has significant experience in advocating for the value of prevention activities such as NDPP and budgetary policies that will allow policymakers to see the long-term value of prevention activities such as NDPP.

HLC also convenes the Confidentiality Coalition, a broad group of organizations representing the entire healthcare system. The Coalition advocates for policies and practices that safeguard the privacy of patients and healthcare consumers while at the same time supporting the essential flow of patient information that is critical to the timely and effective delivery of healthcare, improvements in quality and safety, and the development of new lifesaving and life-enhancing medical interventions.

### **Support for Expanded Access to NDPP**

HLC applauds CDC for its work to deliver and expand NDPP to reach Americans at risk for type 2 diabetes. We strongly support the proposed modifications that anticipate allowing innovative new delivery models of NDPP to receive recognition through DPRP. The CDC's embrace of effective new forms of NDPP is encouraging to HLC members eager to work with payers to expand access to NDPP. We support efforts by the CDC that will allow NDPP programs to align with and interact with the current, traditional healthcare delivery system, and as the program is expanded, we anticipate that increasing numbers of payers will seek out DPRP-approved providers to provide this crucial benefit. These innovative new models will give consumers greater access to wider varieties of offerings and expand opportunities for the vast number of Americans at risk for Type 2 diabetes to seek and receive the support they need to prevent the disease.

### **Data Collection**

While we applaud the steps taken to broaden access to NDPP, we are concerned that the proposed level and specificity of required data collection could inhibit some entities from participating in DPRP based on potential violations of the HIPAA privacy rule. Many of the entities who are being asked to provide data under this program will be covered entities or business associates under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy and security rule. The HIPAA privacy rule prohibits covered entities and their business associates from disclosing identifiable patient information outside of specific defined areas, such as treatment, payment and health care operations. The disclosures sought under this program may not be permitted under these rules (Or may present sufficient compliance concerns for companies to be hesitant to participate). Furthermore, when using or disclosing protected health information for treatment, payment and healthcare operations, the HIPAA privacy rule requires that a covered entity make reasonable efforts to limit itself to "the minimum necessary" to accomplish the intended purpose of the use or disclosure [45 CFR 164.502(b)]. We have significant concerns about whether this program has been tailored to this requirement.

Under DPRP, CDC currently collects patient-level information from organizations providing NDPP services. This information is not de-identified to the extent required by HIPAA. For example, including date of service is not permissible under HIPAA deidentification standards. HLC is concerned that entities subject to the HIPAA privacy rule will not be able to participate in the expansion of NDPP unless this data is de-identified consistent with HIPAA's requirements.

Consequently, we recommend that CDC reconsider the level of patient data collection necessary for program evaluation. As an alternative, aggregated performance or outcome data could provide for the necessary evaluation of program performance and allow participation by HIPAA-covered entities. We applaud the motivation of CDC to perform as thorough an analysis of quality control, quality assurance, and effectiveness evaluation as possible, but believe that the broad implementation of the NDPP program is the first priority, and we should take care not to create any unnecessary barriers to program expansion.

Effective treatment of diabetes represents a major opportunity for healthcare savings because it is prevalent, well-understood, and its comorbidities are preventable and costly to treat. We applaud and support the CDC's continued efforts to extend these benefits to the vast numbers of at-risk Americans. Thank you for this opportunity to comment. If you have any questions, please do not hesitate to contact me at [tgrande@hlc.org](mailto:tgrande@hlc.org) or 202-449-3433.

Sincerely,

A handwritten signature in cursive script that reads "Tina O. Grande".

Tina Olson Grande,  
Senior Vice President for Policy

CC: Patrick Conway, Center for Medicare and Medicaid Innovation, CMS

CC: Christina Heide, Office for Civil Rights, HHS

CDC Response

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Tina Olson Grande  
Senior Vice President for Policy  
Healthcare Leadership Council  
750 9th Street, NW  
Suite 500  
Washington, DC 20001

Dear Ms. Grande:

Thank you for taking the time to review and comment on the CDC Diabetes Prevention Recognition Program (DPRP) Standards. The Division of Diabetes Translation appreciates your commitment to improving the DPRP Standards. All of your comments were carefully considered. Included with this letter you will find specific responses to the suggestions and remarks outlined in your letter dated June 10, 2014.

With the growing number of new cases of type 2 diabetes, it is vital that we continue to implement proven interventions for preventing or postponing this serious disease. The DPRP is an important part of assuring that we meet the goal of reducing new cases of type 2 diabetes. Again, thank you for your interest in the DPRP.

Sincerely,

Division of Diabetes Translation  
Centers for Disease Control and Prevention

**Note:** (C) indicates a comment, suggestion or request for clarification from your organization; (R) indicates a response from CDC (responses are also in blue font)

(C) Support for Expanded Access to NDPP

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(R) Thank you for your comment. We are glad that you approve of the additional models of delivery.

(C) Data Collection

While we applaud the steps taken to broaden access to NDPP, we are concerned that the proposed level and specificity of required data collection could inhibit some entities from participating in DPRP based on potential violations of the HIPAA privacy rule. Many of the entities who are being asked to provide data under this program will be covered entities or business associates under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy and security rule. The HIPAA privacy rule prohibits covered entities and their business associates from disclosing identifiable patient information outside of specific defined areas, such as treatment, payment and health care operations. The disclosures sought under this program may not be permitted under these rules (Or may present sufficient compliance concerns for companies to be hesitant to participate). Furthermore, when using or disclosing protected health information for treatment, payment and healthcare operations, the HIPAA privacy rule requires that a covered entity make reasonable efforts to limit itself to "the minimum necessary" to accomplish the intended purpose of the use or disclosure [45 CFR 164.502(b)]. We have significant concerns about whether this program has been tailored to this requirement.

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(R) The Centers for Disease Control and Prevention is an agency of the US Department of Health and Human Services and is a public health authority as defined by the Health Insurance Portability and Accountability Act (HIPAA), Standards for Privacy of Individually Identifiable Health Information; Final Rule (Privacy Rule)[45 CFR § 164.501]. Pursuant to 45 CFR § 164.512(b) of the Privacy Rule, covered entities may disclose protected health information to public health authorities " . . . authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions . . . ." The DPRP is a public health activity as described by 45 CFR § 164.512(b) referenced previously, and is authorized by Section 399V-3 of the Public Health Service Act. The information being requested represents the minimum necessary to carry out the public health purposes of this program pursuant to 45 CFR § 164.514(d) of the Privacy Rule. The Privacy Rule provides that covered entities " . . . may rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purposes when making disclosures to public officials that are permitted under 45 CFR § 164.512, if the public official represents that the information requested is the minimum necessary for the stated purposes(s)." CDC considers the requested information to be the minimum necessary for the stated purpose of the DPRP.