April 15, 2014

Karen Matsuoka, Ph.D
Director, Health Services Infrastructure Administration
Department of Health and Mental Hygiene
300 W. Preston St.
Baltimore, MD 21201

Re: Comment on Maryland's State Healthcare Innovation Report submission to the Center for Medicare and Medicaid Innovation (CMMI), March 31, 2014

Dear Dr. Matsuoka:

The nursing community, represented by the organizations that have signed onto this letter, appreciates the opportunity to comment on the above-referenced State Innovation Model Report (SIM Report). The Department of Health and Mental Hygiene (DHMH) has submitted this report to the Center for Medicare and Medicaid Innovation (CMMI) as a final report for the planning grant. As we understand, DHMH plans to submit an application to CMMI for implementation funds.

We endorse many of the goals embedded in the SIM Report regarding improved patient outcomes, and we share DHMH's commitment to developing innovative care delivery models to meet the challenges facing our health care delivery system. As nursing representatives discussed with the Department in the fall, we urge DHMH to make a more careful delineation of the roles of the health care delivery team members. The SIM Report raises a number of significant patient safety and patient outcome concerns that we have outlined in this letter.

1. The role of nurses is insufficiently addressed or integrated into the model

According to the SIM Report, the CIMH design is derived from the Health Quality Partners' Advanced Preventive Services (HQP) model developed and implemented for the Medicare coordinated care demonstration program. HQP is a community-based nursing approach in which nurses develop a care plan based on a comprehensive needs assessment that includes social, economic, and environmental determinants of health. Nurses conduct the assessment, prepare the plan, and then manage, administer, and deliver interventions through office, home visit, or telephone contacts with the client, as appropriate. The SIM Report envisions straightforward adoption of the HQP model as the "minimum standard for all community-based clinical care coordination for Medicare FFS or dual-eligible patients," and that it "will be replicated or adapted in its entirety" for other patient populations. (SIM Report, p. 51.)

Although nurses play a central role in the HQP concept, the SIM Report focuses almost exclusively on community health workers (CHWs). We believe that there needs to be an increased focus on registered nurses and other licensed health care practitioners in order for the model to be successful. Indeed, registered nurses are rarely mentioned in the SIM Report outside of sections describing the HQP program and its evaluation results, or in passing references where their specific contribution within the CIMH

framework is unclear. The asthma intervention example, for instance, includes an "RN" (not otherwise defined) providing unspecified "services" as a member of the community health hub team. (SIM Report, pp. 85-87.) A single sentence refers to supervision by "a licensed clinician, nurse, or social worker" of a CHW providing direct care. (SIM Report, p. 61.) The structure and staffing of care teams, supervision requirements, and financing of the team are not addressed. Registered nursing roles—including functions such as clinical care coordination—are either not discussed or reassigned to CHWs (see SIM Report, p. 115, which gives participating CIMH practices the option of employing a nurse or CHW to coordinate clinical care). Also missing is consideration of how the existing array of allied health care professionals, such as certified nursing assistants and certified medical technicians, fits into the model and the extent to which they already provide, or may be trained to provide the services foreseen for CHWs. There is almost no discussion of other licensed health care professionals – including physicians, licensed certified social workers, license certified social worker – clinical, and dietetic practitioners – who would be critical members of the health care team. Instead, the workforce discussion is entirely confined to the training, certification, and employment of CHWs.

The full and thoughtful integration of registered nurses in the CIMH framework is critical to its success, as is an acknowledgement of the contributions of other health care professionals who are part of a care team. Optimal use of the existing health care workforce at all levels in the new delivery model will safeguard patient welfare, capitalize on established systems and relationships, and avoid inappropriate or overlapping assignation of responsibilities that would jeopardize attainment of program goals.

2. SIM Report is Not Implementable: Provision of direct care by CHWs violates licensure laws for health care practitioners

The SIM Report contemplates permitting community health workers to perform certain tasks that do not require "extensive clinical skills and knowledge" as a way of lowering costs. (SIM Report, p. 107.) Those tasks include "ongoing assessments and screenings," "education and self-management training," "assessment and counseling for behavior change," and "stress management education and counseling." (SIM Report, p. 65.) However, the report fails to recognize that each health occupation has a detailed scope of practice whose parameters are strictly determined by statute and regulation. Delegation of clinical duties to CHWs—and oversight of CHW performance of these duties—would violate Maryland law governing the registered nursing scope and standards of practice, in addition to the scope and standards of practice pertaining to other health occupations.

COMAR 10.27.11 sets out the requirements for delegation of registered nursing functions. It expressly prohibits delegation of "evaluation of the client's progress, or lack of progress, toward goal achievement." (COMAR 10.27.11.05(A)(5).) In instances where delegation is permitted, the registered nurse must make a determination that takes into consideration specified factors. For treatments of a routine nature, for instance, the delegating nurse must weigh whether the nurse staffing ratio allows for close supervision. (COMAR 10.27.11.05(B)(3)(b).) Most importantly, delegation is permitted only on case-by-case basis: a delegated task may not become a part of regular job duties. (COMAR 10.27.11.05(E).) The requirements for supervision by the delegating nurse are also outlined in detail, and include the registered nurse's ready availability, regular visits to reassess whether the client's health status warrants someone

other than a registered nurse to perform a delegated act, and an evaluation of the competence of the person to whom a task is delegated. (COMAR 10.27.11.04.) These rules apply to all registered nurses who supervise unlicensed and/or certified individuals, regardless of the program or facility in which they are employed (see, e.g. Medicaid Living at Home waiver, COMAR 10.09.55.14; Increased Community Participation Program, COMAR 10.09.81.14).

It would appear that the regulatory restrictions on the delegation of nursing tasks conflicts with a delivery model that authorizes CHWs to provide direct care under registered nursing supervision. This will likely also be the case for the other "licensed clinicians" and social workers foreseen as CHW supervisors. The SIM Report as currently drafted cannot be implemented without significant statutory and regulatory amendment to align the registered nursing (among others) scope of practice and licensure standards with the proposed duties of this new health professional. **It should be emphasized that the overarching purpose of these laws is to protect the public, and any revisions must contemplate the ramifications for patient safety, as discussed further below.**

3. Patient safety is subordinated to cost considerations

The SIM Report deems certain direct care tasks performed by registered nurses or allied health professionals not to "require extensive clinical skills and knowledge" and, therefore, potentially suitable for reassignment to CHWs in the interest of lowering intervention costs. This approach, which subordinates patient safety to financial considerations, is contrary to the purpose of state regulation of health care occupations. Health care professional laws establish standards for education, training, and skills necessary for the safe and effective provision of care within a given scope of practice. The law does not accommodate concepts such as "extensive"—rather, clinical skills and knowledge must be sufficient, as determined by the regulatory boards and accreditation bodies, to ensure positive outcomes. It should be noted that some of the tasks suggested for CHWs are explicitly reserved for certain licensed professionals precisely because patient safety is the primary concern. The inference that the performance of "ongoing assessments and screening" does not demand clinical judgment, or that "ongoing medication reconciliation and adherence monitoring" (SIM Report, p. 27) is relatively undemanding of professional expertise is inconsistent with the determinations made by health occupation boards, accepted standards of care, and the guidance of national health care quality entities. For example, the Agency for Healthcare Research and Quality (AHRQ) considers medication reconciliation to be a patient safety issue and emphasizes the importance of instituting a sound, systematic process of medication comparison, unintended discrepancies, and resolution to the achievement of patient safety goals. (See the MATCH Toolkit published by AHRQ.) The Joint Commission (TJC) National Patient Safety Goal on Reconciling Medication, which applies to all types of accredited programs, was revised in 2011 to include as an element of performance that medication comparison is conducted by a qualified individual. (NPSG .03.06.01.)

Furthermore, it is important to note that the statutory authority for community health hubs is not yet in place, and that appropriate supervision will additionally require the promulgation of regulations. The SIM Report takes into consideration the establishment of a basic operating infrastructure for the CIMH program, the Public Utility, development of the Operational Management System, and an RFP process. (SIM Report, p. 122.) However, the Report does not consider associated statutory and regulatory steps in its

timeframe. We are looking forward to the CHW workgroup authorized by the General Assembly, but the workgroup has yet to be established. .Any rules, whether statutory or regulatory, must be in place for effective oversight of the CIMH model prior to implementation. Therefore, we highly recommend taking into account existing statutory and regulatory frameworks when shaping the SIM Model.

Finally, the SIM Report proposes "applied R&D trials," one aspect of which will be "to thoughtfully experiment with adjusting workforce roles, in particular greater use of CHWs to deliver community interventions." (SIM Report p. 64.) This is also described as determining "the substitutability of CHWs" in the nursing-led ASP model (SIM Report, p. 96). Moreover, there is a "ramp up" period foreseen that implies continued testing of the model during an initial implementation phase. (SIM Report, p. 124.) Testing that involves "intentional variations to staff models" (SIM Report, p. 64) would breach existing scope of practice laws—by definition, jeopardizing patient safety, in addition to creating irreconcilable conflicts for professional staff who could face disciplinary action—and, therefore, would be impermissible.

4. Insufficient and inconsistent regulatory structure

Equally troubling from a patient safety perspective is that the community health hubs responsible for oversight, management, and deployment of community health teams—and, in some cases, direct hiring and training of staff—will be certified by a specially created CIMH Public Utility that is jointly administered by the Health Systems and Infrastructure Administration in DHMH and the MHCC. This would set up a fragmented regulatory system in which certain entities providing in-home services would have to meet standards and comply with protocols established by the Office of Health Care Quality (OHCQ), while those licensed as community health hubs would not.

OHCQ regulates home health and residential services agencies under a system that encourages informal as well as formal comments on policy, provides for public participation through workgroups, and incorporates a complaint and investigation process. The regulatory framework governing ambulatory care services in the home is not only well established, but it is designed to be patient centered—a stated purpose of the CIMH model. Creation of a comparable system for community health hubs under the CIMH Public Utility would demand a significant investment of resources that is not contemplated in the SIM Report. Nonetheless, having two separate regulatory structures is unnecessarily complicated, confusing for clients (particularly given the similarity of functions for home health aides and CHWs) as well as providers, and will undermine the efficacy of oversight intended to protect public welfare. The regulation of in-home services should be under a single jurisdiction—namely, OHCQ.

Conclusion

We reiterate our support for the concept of an integrated community-health care model that incorporates interventions designed to address socio-economic, demographic, and environmental influences on health status and thereby improve outcomes. However, the SIM Report in its current form raises numerous concerns and leaves many questions unanswered on aspects that are essential to its success. We strongly recommend engaging the participation of a broad range of registered nursing professionals (just 1 nursing representative was included among the total 58 stakeholders consulted

during development of the Report), representatives of the other health care professions, and the health occupations boards to explore solutions to the issues we have identified.

Thank you for considering our comments. Should you have questions or need additional clarification, please feel free to contact Ms. Robyn Elliott, public policy consultant for the Maryland Nurses Association (MNA), at (443) 926-3443 or relliott@policypartners.net. MNA will coordinate with the other signatories on gathering any information needed by DHMH.

Sincerely,

Maryland Nurses Association
American Psychiatric Nurses Association – Capital Chapter
Maryland Academy of Advance Practice Clinicians
Nurse Practitioner Association of Maryland
Philippine Nurses Association, Maryland Chapter

cc: Dr. Laura Herrera, Deputy Secretary of Public Health Services
Ms. Patricia Noble, Executive Director of the Maryland Board of Nursing
Ms. Gloria Jean Hammel, Executive Director of the Board of Social Work Examiners
Ms. Tracey DeShields, Executive Director of the Board of Professional Counselors
Ms. Marie Savage, Executive Director of the Board of Dietetic Practitioners
Ms. Lorraine Smith, Executive Director of the State Board of Psychological Examiners
Dr. Tricia Nay, Executive Directof of the Office of Health Care Quality