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McKESSON
Empowering Healthcare

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Dr. David Brailer, M.D.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 517D
200 Independence Avenue, S.W.
Washington, DC 20201

Via Email at NHINRFI@hhs.gov

Attention: NHIN RFI Responses

Dear Dr. Brailer,

On behalf of McKesson Corporation (hereinafter "McKesson"), we are pleased to respond to your Request for Information, dated November 15, 2004, regarding the establishment, implementation and support for a National Health Information Network (NHIN). As the world's largest healthcare information technology company, we are submitting comments which reflect the unique breadth of our experience and expertise, our broad solution set and the range of our customers' perspectives on these important issues. We are also endorsing and referencing comments submitted by industry organizations and associations to which we belong. We appreciate the opportunity to engage in a participative process in this most important initiative.

As a Fortune 16 corporation dedicated to providing information technology, care management services, automation, medical supplies and pharmaceutical products to virtually every segment of the healthcare industry, we understand both the challenges that must be overcome in order to achieve interoperability and the magnitude of the opportunity for significant quality and efficiency improvements that can be realized when such interchange is achieved. McKesson touches the lives of over 100 million patients in healthcare settings that include more than 5,000 hospitals, 150,000 physician practices, 10,000 extended care facilities, 700 home care agencies, and 25,000 retail pharmacies. With our technology solutions in 65% of U.S. health systems, McKesson is actively engaged in the transformation of healthcare from a system burdened by paper to one empowered by interoperable electronic solutions that improve patient safety, reduce cost and variability of care and improve healthcare efficiency. Our success in supply chain automation and electronic transaction processing and our experience in e-prescribing exemplify the benefits that can be derived from sustained efforts to improve stakeholder communication and to eliminate duplication of efforts in the healthcare delivery process.

McKesson has established a strong record of support and involvement in important federal and state health initiatives. We have been a pioneer in the introduction of drug savings cards to help lower the costs of pharmaceuticals through our administration of the successful Together Rx ™ card and our subsequent introduction of the CMS-endorsed Rx Savings Access™ Card. The Together Rx™ card has delivered over $578 million in savings since June 2002 to more than 1.48 million low-income seniors. McKesson's Rx Savings Access™ Card is providing Medicare beneficiaries with an average savings of 15-25% on the most commonly prescribed medicines and is accepted by over 95% of pharmacies nationwide. To date, more than 223,000 Medicare-eligible seniors are enrolled in this card and have realized over $40 million in savings on their prescription drugs.

McKesson has also taken a proactive approach to providing disease management programs for commercial, Medicaid and Medicare populations where we leverage our experience with patient services, pharmacy management and healthcare quality improvement activities. In seven states where we provide disease management services to Medicaid patients, those states are saving approximately two dollars for every dollar spent with McKesson, while improving both the health status of the patient population and physician satisfaction with the program. Late last year, we were awarded one of the Chronic Care Improvement Program (CCIP) demonstration projects by CMS for Medicare beneficiaries.

We are pleased to expand this record of support for innovative national and state health initiatives through our response to this Request for Information.

Our response consists of the following three components:

I. **Endorsement of the Collaborative Response**: McKesson has been an active participant in the development of the Collaborative Response authored by Connecting for Health. This Collaborative Response incorporates responses from a diverse group of participating organizations, including AHIMA, AMIA, ANSI HISB, CITL, Connecting for Health, eHealth Initiative, HIMSS, the HIMSS EHR Vendor Association, HL-7, IHE, Internet2, the Liberty Alliance and NAHIT (the Alliance). We are pleased to endorse and support the principles and perspective advocated in the Collaborative Response that elaborates on the essential consensus: "…that general adoption of a small set of critical tools can permit rapid attainment of an interoperable information environment that supports modern healthcare practice." We have attached the Collaborative Response in its entirety to our response to reflect the consensus that underlies our specific elaborations, clarifications and additional comments.

II. **Endorsement of the HIMSS EHR Vendor Association Response:** McKesson actively contributed to and endorses the additional comments authored by the

HIMSS EHR Vendor Association. In addition to providing an application-oriented view of systemic interoperability, the EHR Vendor Association has focused on a viable roadmap for implementation that prioritizes efforts and provides a timeline for achieving benefits. We believe these comments further clarify and extend the overall systems approach envisioned by the authors of the Collaborative Response and enrich that response regarding considerations necessary for application developers to take advantage of the capabilities of the NHIN. We have attached the HIMSS EHR Vendor Association response to underscore our fundamental agreement with these positions.

III. **McKesson Response:** We are offering observations, clarifications and elaborations to the two referenced responses to reflect the "360 degree view of healthcare" that we have through the breadth of our product and service offerings which are utilized by a broad array of customers and partners.

RFI Responses:

Question 1: Working Definition of a National Health Information Network

McKesson endorses the working definition of the NHIN as described in the Collaborative Response (CR) and then amended and further clarified by the EHR Vendor Association (EHRVA). We agree that the NHIN should be viewed as a "network of networks," linked one to the other into a single logical whole by the common adoption of the standards, policies and services contained in the Common Framework and specified by the Standards and Policy Entity that provides the central authority for assuring compliance. We also agree with the comments added by the EHRVA which support a network architecture that is as "thin" as possible. The CR describes the NHIN in its totality, including all the components necessary for its deployment and operation as well as the applications and data stores that may evolve from its implementation. The EHRVA further clarifies those components of the NHIN that are network components (these represent the "thin" structures necessary to establish connectivity between connected applications, systems and sub-networks) and those components which represent applications or activities that may arise from the availability of the network.

Although both perspectives are necessary, it is very important to distinguish between the capabilities of the national network and those of the applications which connect to the network. While it is important to look at the NHIN in its totality in order to understand its operation and its value, McKesson endorses a more traditional technical architecture which specifies all details from physical connectivity through the application layer. Our comments throughout this response distinguish between those policies, standards and services that are essential network components and the applications that provide specific functionality and access for particular users and stakeholders.

We believe that the concept of sub-networks provides a rich descriptor for the wide variety of networks that may evolve as local components of the NHIN. While the CR acknowledges that large provider networks like Kaiser or the Department of Veterans' Affairs could play a major role in providing connectivity to individual stakeholders, McKesson believes that Integrated Delivery Networks (IDNs) can also fulfill this important role. Concerns over the "proprietary" nature of IDNs will diminish if the sponsored networks comply with the Common Framework and are accessible and interoperable with all other sub-networks. This approach, combined with "safe harbor" provisions for qualifying sub-nets, will encourage the formation of network nodes and dramatically increase stakeholder access to the NHIN. The NHIN should also allow for the integration of existing value-added network and EDI communications infrastructures, in addition to Regional Health Information Organizations ["RHIOs"], Local Health Information Infrastructures ["LHII"] and other public community network models. The use of existing network infrastructures will help to enable and expedite the implementation of the proposed federated security model.

Given these architectural and conceptual considerations, McKesson envisions a NHIN undertaken and constructed within a framework predicated on the following "guiding principles":

Guiding Governance Principles
The NHIN will be based upon open internet technologies and standards rather than proprietary centralized technologies and formats.

The NHIN will establish a single governance body, the Standards and Policy Entity (SPE) which will charter and oversee the development of any required standards. The NHIN will be governed by these interoperability and compatibility standards.

The NHIN shall establish an ubiquitous trust network, which provides clear policies for access to sensitive information, use of that information and for the enforcement of these policies. The trust network is needed to build voluntary participation in the program and will allow all participants and stakeholders to govern, monitor and engage in the exchange of information, services and payments.

Guiding Social Principles
Healthcare is a fundamentally collaborative process that requires many stakeholders to achieve consensus on a course of action. For example, a patient's care is usually determined by a combination of physician recommendations, patient preference and payor coverage. Unfortunately, healthcare IT systems to date have largely been modeled after the command and control systems used for manufacturing, financial services and supply chain management; none of these promote or enable collaborative

decision support. The widespread adoption of internet connectivity and technologies has driven the evolution of highly collaborative systems that in turn have spawned large economically and socially sustainable communities. These learned principles must be applied to the interoperability standards that form the core of the NHIN.

While the technical perspective of the NHIN focuses on the aggregation of sub-networks, the collaboration model for the NHIN will be based on the formation of communities. Participants will belong to multiple communities, each with its own shared interests, size, policies and financial models. The NHIN will sponsor the development and governance of a meta-model capable of supporting communities via a common governing infrastructure that is, in turn, built on the trust models previously mentioned.

Guiding Economic Principles
The NHIN recognizes that network participants will have a wide range of economic and technical capabilities. Global requirements and standards should include all constituents in either category.

The NHIN should take advantage of private investments and market-driven solutions as well as public domain solutions for some of the most common NHIN systems and operations. For example, while the NHIN provides the connectivity framework of contributing RHIOs, the RHIOs should utilize common applications or public shareware to access the NHIN, thus providing the broadest possible access to the NHIN from the broadest possible base of providers with minimal regard to specialized application software development.

Guiding Technical Principles
Ownership of and access to information, services and payments will be governed by a set of universal standards that ensure security, transparency, traceability, non-repudiation, authenticity, and access control.

The NHIN cannot predict the evolution of the healthcare, business and social models that will evolve with widespread adoption of the NHIN. Therefore, the underlying systems will be based upon open, extensible, platform-independent standards that govern connectivity, interoperability and relationships.

Successful internet systems rely on de-centralized data storage supported by centralized indexing mechanisms. This paradigm will apply to the management of healthcare information, NHIN communities, identification strategies, payment and other systems.

Finally, these guiding principles represent a pragmatic vision for connecting the many stakeholders of the American healthcare system in a national network that is designed to address the concurrent goals of improving the quality and delivery of healthcare.

This framework requires minimal initial investment, minimizes operational costs and promises the greatest benefits in the shortest time frame for stakeholders and for the nation.

Question 2: What type of model might be needed to have a NHIN that: allows widely available access to information, enables interoperability, protects personal data, allows vendors and other technology partners to be able to use the NHIN in the pursuit of their business objectives?

McKesson strongly endorses the issues detailed in the CR. We believe that it is especially important for authorized providers and payers to have access to accurate and reliable patient information as well as the ability to exchange that information. To assure patient safety, it should in fact be an obligation of the NHIN to insure that authorized people who access this information are able to see the entire patient record. To that end, we would support the use of a common patient identifier. The use of a unique and consistent patient identifier would greatly enhance the accuracy, reliability and completeness of a patient's records and is necessary to protect the patient from errors that might result from missing or inaccurate data. We acknowledge and understand the privacy and security concerns inherent in a common or national patient identifier and would support the necessary safeguards to address these concerns. We believe that the EHRVA and other participating stakeholder organizations should agree upon standards to identify patients and a proposal to support a common identifier which would then be presented for discussion with appropriate governmental bodies.

McKesson believes that the NHIN should be built upon existing infrastructure without the requirement for "new wires" or the creation of new platforms, and largely upon existing standards. Existing standards need to converge to support common well-defined workflows in order to accelerate interoperability. These workflows and the data they require should be specified by the end users who will be expected to adopt and use them.

Question 4: What type of framework could be needed to develop, set policies and standards for, operate, and adopt a NHIN?

We endorse the five key components of the NHIN identified by the CR. We agree that the NHIN will function largely like the Internet, without the requirement for a centralized organizing and operating entity. Certain functions will be centralized, but those policies and standards can be derived from a public-private collaborative that identifies and establishes the implementation process for the standards and policies. The NHIN can be self-regulating, much like the Internet, so that failure to conform to the Common Framework will result in a lack of ability to connect or interoperate with other resources connected to the NHIN. This framework requires little to no long-

term regulatory or certification authority in order to sustain the operating capabilities of the NHIN.

Question 5/6: What kind of financial model could be required to build/operate and sustain a functioning NHIN?

McKesson agrees with the CR that the NHIN must create real value for its participants. Without value, no model for financing will prove sustainable. The sustainability of the NHIN will only be assured when the value created is aligned with the costs and risks borne by those who adopt and implement healthcare information technology. The federal government should ensure that the benefits derived from the adoption and use of information technology are shared on an equitable basis with those who produce the value. Financial models could be based on a combination of reimbursement, both by the government and private carriers, for specific costs incurred and for demonstrated compliance with NHIN standards. Alternatively, a more generalized reimbursement model that is based on healthcare encounters should be considered. As the world's largest payer, the government should assume a leadership role in this area.

Question 11: How could a NHIN be established so that it will be utilized in the delivery of care by healthcare providers, regardless of their size and location, and also achieve enough national coverage to ensure that lower income rural and urban areas could be sufficiently served?

McKesson believes that the NHIN and associated applications that enable access to patient information should complement the workflow of physicians and their office staff. The standards and policies associated with this initiative can not impose an undue burden on providers or substantively change physician or office practice behavior. Otherwise, clinician acceptance will be compromised. While this response primarily addresses the technology required to support the NHIN, the administrative burdens inherent in acquiring all patient medical information and necessary patient authorization must be carefully evaluated with regard to their impact on provider practice. In order to achieve broad and persistent use of the NHIN, reasonable implementation of rules that pertain to individual healthcare encounters will be of paramount importance. Providers must be able to focus on the patient and do so with minimal impact on their routines or their supporting staff.

Question 12: How could community and regional health information exchange projects be affected by the development and implementation of a NHIN? What issues might arise and how could they be addressed?

McKesson believes two major issues might arise. First, given the broad range of initiatives already underway across the country, it is inevitable that some of these current efforts will be slowed and that some amount of rework will be required to

bring them into compliance with emerging standards, services and policies. Second, as the SPE and network participants formulate policy, establish standards and implement systems, there will certainly be operational breakdowns, approaches that require rethinking, and other failures. The SPE must anticipate and plan for recognizing and addressing these issues in a timely and effective manner that promotes learning, positive corrective action and minimal disruption. The timely and effective communication of new policies and standards to the stakeholders will be a key success factor.

Question 15: How should the development and diffusion of technically sound, fully informed interoperability standards and policies be established and managed for a NHIN, initially and on an ongoing basis, that effectively address privacy and security issues and fully comply with HIPAA?

The SPE must establish a clear policy that ensures any adopted standard is not burdened with intellectual property licenses that are royalty bearing or discriminatory. This royalty-free licensing policy must include the following elements:

- disclosure of relevant existing or proposed patents by any participant recommending a standard
- agreement by participants to license all essential claims to interoperability standards on a royalty-free non-discriminatory, irrevocable basis.

These measures will ensure that no one organization has the ability to exert undue control over the Common Framework or the Standards and Policy Entity.

Question 18: What roles and relationships should the federal government take in relation to how interoperability standards and policies are developed, and what roles and relationships should it refrain from taking?

As envisioned by the CR, the SPE would have ultimate responsibility for the specification and development of needed standards and policies. The SPE would be created and managed as a public-private entity with a fairly broad charter that would address the essential responsibilities described in this response plus any additional responsibilities that may become necessary from the evolution of the NHIN. The federal government's role relative to the SPE encompasses three major responsibilities. First, the federal government, as both provider of healthcare services and payer for a large segment of the population, needs to have representation on the SPE adequate to reflect its interests as both payer and provider. Second, the federal government needs to provide the necessary standing to the SPE to ensure its legitimacy as arbiter and enforcer of necessary policies and standards. Third, to ensure the rapid launch and prompt development of the necessary deliverables, the federal government should provide seed funding to the SPE and on-going funding as

necessary to ensure the attainment of its objectives. Federal responsibilities should also include the funding of demonstration projects, the assurance of NHIN access in rural and underserved areas, and the development of incentives and use of the NHIN and of the critical applications that make use of it. We do not foresee a long-term regulatory role for the federal government other than to provide oversight of the NHIN to ensure that it is achieving its anticipated benefits.

Question 21: Are there statutory or regulatory requirements or prohibitions that might be perceived as barriers to the formation and operation of a NHIN, or to support it with critical functions?

McKesson believes that the potential benefits of a connected healthcare system require a new look at existing government policies that may hinder widespread adoption of healthcare information technology. Existing anti-trust, fraud and anti-kickback laws should be reviewed to determine if compliance with NHIN policies and standards could create a "safe harbor" exemption to encourage adoption and dissemination of healthcare technology. In addition, HHS, CMS and ONCHIT should investigate whether national policies and standards could be advanced to minimize or eliminate the conflict between national and state policies and standards. Since many medical "communities" are not limited to a single state's borders, resolving differences between state laws and federal policy will be required to speed adoption and implementation. If these concerns are adequately resolved, many integrated delivery systems would make the necessary investments to comply with the Common Framework in order to take advantage of the benefits of a connected healthcare system.

Question 23: Describe the major design principles/elements of a potential technical architecture for a NHIN. This description should be suitable for public discussion.

We strongly endorse the major design principles and elements as clarified in the EHRVA response. In particular:

The NHIN should be deployed by utilizing an approach that allows the incremental deployment of services to provide health information exchange.

- The NHIN should be deployed with a set of services that facilitates the exchange of basic patient healthcare information between End-Point Systems to improve the delivery of patient care and incrementally enhances these services with increasing interoperability and transaction innovation over time. Under this model, the capability of the NHIN expands in direct proportion to the information that is being exchanged. In the initial phase, this information would be limited to document exchange that gives providers a synopsis of crucial patient data but contains only minimal discrete information. In later phases, we foresee the extension of coded allergy, problem list and medication information, all of which

is necessary to achieve real-time decision making. Additionally, this extension of coded information will support an improved aggregation of essential patient information that today suffers from a too narrow view of the patient.

- The roadmap for deployment of NHIN services should be as specific as possible in order to provide the private sector with sufficient time to plan and implement the defined services.

The NHIN should be deployed by encouraging sub-networks (RHIOs or RHINs) to be created, but they should all use the same "Common Framework" of interoperability standards and polices.

- An essential component of establishing interoperability standards (via the Common Framework) will be the agreement on a common clinical vocabulary model. We endorse the use of SNOMED® clinical terminology (SNOMED CT®) as the common clinical vocabulary model that could be adopted without extensive licensing requirements for stakeholders, assuming that the current licensing agreement with the National Library of Medicine is extended. SNOMED CT will significantly enhance the accuracy of coded information while reducing the cost and complexity of deployment.

Question 24: How could success be measured in achieving an interoperable health information infrastructure for the public sector, private sector and health care community or region?

In our response to Questions 5 and 6 of the RFI, we stated our strong belief that any sustainable model for the NHIN must produce real benefits for its stakeholders. While the CR details some global success criteria for the NHIN, McKesson would like to recommend a stakeholder model for measuring and insuring its success.

For the public sector: This RFI was introduced with the concept that an interoperable healthcare system would create significant benefits in terms of both improved quality of care and improved efficiency in healthcare delivery. An undertaking of this magnitude should then be measured in terms of its impact on system-wide measures of cost and quality. Over the last decade, the public sector has developed sufficient measures that can and should be monitored to ensure that the anticipated benefits of the NHIN are realized. McKesson believes that the following success criteria are critical:

- Administrative costs as a percent of total public sector healthcare expenditures
- Percent of total healthcare spending on duplicative or unnecessary care
- Satisfaction of public sector healthcare program beneficiaries

The implementation of a successful NHIN should produce solid evidence that a greater proportion of spending goes to necessary and appropriate care and that the system's efficiency and quality are clearly improved in the eyes of its beneficiaries.

For the private sector: The benefits that accrue to the public sector would pose real benefits for the private sector as well. The success criteria most universal to this sector is containing the rate of cost increase of the healthcare benefit. Appropriate measures should focus on the increase in cost of the healthcare benefit compared to total expense growth. Related but secondary success criteria would include the development of a robust market for innovative healthcare solutions. The creation of a NHIN should enable a broader, more competitive and more robust market for both healthcare delivery options and for information technology solutions. Increased competition can be a major factor in slowing or reducing the cost of the healthcare benefit.

For healthcare stakeholders in a community or region: Measures of success in the community or region can similarly be considered in light of their major shareholders. Providers seek a measurable improvement in the quality of their professional lives. While provider satisfaction can be measured, indirect effects of improved quality and efficiency would be more significant. Providers seek reduced malpractice insurance premiums, shortened work days and increased time spent on the clinical aspects of their practice. Patients seek greater and more convenient access to care, a more streamlined care process and a reduction in the growth of the percentage of their personal income that is dedicated to healthcare premiums, services or products.

All of these measures are global measures, capable of a wide range of influence from many sources. The impact of the NHIN must be seen in terms of its ability to impact the healthcare system from a macro basis. If it fails to substantively impact macro measures of that system's cost, quality and satisfaction, then the effort has failed to achieve its ultimate objectives.

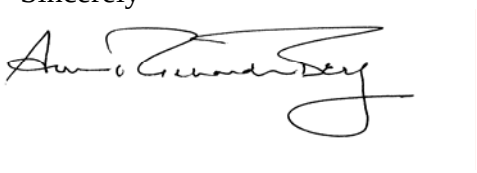
Conclusion

McKesson is pleased to have the opportunity to respond to this RFI for a National Health Information Network, both as a leader in the healthcare information technology industry and as a member of the dedicated teams that developed the Collaborative Response and the HIMSS EHR Vendor Association response. Through these efforts, we have sharpened our focus on the essential requirements to achieve systemic interoperability of healthcare information technology and have developed improved working relationships with the myriad of stakeholders that will be required to achieve this interoperability. We hope that these supplemental comments will be helpful to you in developing and advancing a comprehensive vision for interoperability that will make a measurable and sustainable improvement in our healthcare delivery system. McKesson stands ready to

work with you and your staff in the Office of the National Coordinator for Healthcare Information Technology to help make this vision a reality.

If you have any questions regarding this response, please contact Mike Kappel at (404) 338-3833, or via email at mike.kappel@mckesson.com or me at (415) 983-8494 or at ann.berkey@mckesson.com.

Sincerely



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