Submitted Electronically

To: Minister for Medical Care
De heer drs. M.J. van Rijn
Ministry of Health, Welfare, and Sport
Postbus 20350
2500 EJ Den Haag

Date: 10 June 2020
Re: Wetsvoorstel Elektronische Gegevensuitwisseling in de Zorg

Dear Minister van Rijn:

Thank you for the opportunity to participate in the open consultation regarding the Draft Bill on Electronic Data Exchange in Healthcare (GUZ).

Epic is a health information technology developer headquartered in Verona, Wisconsin in the United States, and with a number of offices world-wide, including one in 's-Hertogenbosch. Hundreds of thousands of healthcare providers worldwide, including in the Netherlands, use our electronic patient dossier (EPD) software as the information backbone of their operations to improve patient outcomes and reduce costs.

Epic is, and always has been, committed to standards-based interoperability and to eliminating barriers to information exchange. Epic enabled its customers to lead the first wave of interoperability over 10 years ago with our Care Everywhere solution. This software allows healthcare organizations to exchange patient information, regardless of which EPD system they use. All healthcare organizations in the Netherlands that use Epic already exchange patient data and coordinate care using Care Everywhere and exchange more than twenty five thousand dossiers each month. We expect that number to keep growing.

We strongly support the goals of the draft bill, including the adoption of standards for data exchange to get healthcare providers the information they need to care for patients. Below, we have included an executive summary of our feedback on the draft bill, followed by detailed comments organized by provision. Our feedback draws from our years of experience developing software that supports healthcare providers by facilitating the worldwide exchange of over 5 million patient dossiers every day, and the successes and challenges of similar initiatives in other European countries.

We hope that our feedback will help guide the efforts of the Ministry of Health, Welfare, and Sport in creating a legislative and regulatory framework that promotes sustainable health data exchange while minimizing the costs and burden imposed on healthcare organizations.

We are happy to answer any questions you may have about our feedback. Thank you for your consideration.

Nick Lundien
Director, Epic Netherlands

Martijn Antonius
Director, Epic Netherlands

EXECUTIVE SUMMARY
Epic's Feedback on the Draft Wetsvoorstel Elektronische Gegevensuitwisseling in de Zorg

Epic appreciates the opportunity to provide the Ministry of Health, Welfare, and Sport feedback on its draft bill for health information exchange. The bill seeks to improve the electronic flow of health information by establishing a framework that (1) requires healthcare providers to exchange data electronically for designated use cases, (2) identifies the technical method of exchange, and (3) requires the certification of health IT for certain designated use cases.

We strongly support the Ministry's goal of improving health information exchange. Well-designed data exchange tools empower providers by giving them critical patient information at the right time. Epic has more than a decade of experience developing innovative tools that do just that. We also collaborate extensively with actors across the health ecosystem to create consensus-based technical standards that ensure data is accessible, regardless of which EPD software a provider uses.

We are grateful for the supplemental materials the Ministry has prepared with the intention of providing greater clarity into how the regulatory framework will work in practice. However, the processes outlined in those materials are not referenced anywhere in the draft bill. This lack of guardrails in the draft law will not hold the Ministry accountable to best practices that will be critical to the success of the program. Our detailed commentary focuses on building guardrails into the act that ensure accountability through open processes and collaboration with actors across the health ecosystem.

Require Collaboration with Industry Actors

Our experience enabling interoperability for hundreds of thousands of healthcare providers has shown that exchange initiatives work best when actors across the health ecosystem collaborate and build consensus on solutions for particular use cases. Health IT developers and provider organizations are well positioned to provide the Ministry of Health with expertise that will promote the adoption of technically feasible norms that best meet the needs of front line providers.

Today, there are clear examples of programs that would have benefited from closer collaboration with industry actors through public consultation periods. When we developed support for the BgZ download as part of the VIPP 1 program, Epic and our customers jointly identified 27 issues in the final standard. Fifteen of those issues impeded our ability to complete development and prevented the standard from functioning as intended. Resolving the 27 issues required Nictiz to rush to patch the standard. Ultimately, this delayed the ability of provider organizations to go-live with tools that support the program. In another example, Module 3 of the VIPP 5 program does not include uniform baseline technical standards. This will lead to incompatible custom solutions, and will require extra development effort if it is regulated under Track 2 according to this bill. This outcome could have been avoided with more opportunities for industry actors to provide feedback on the program.

Despite the clear benefit of proactively collaborating with industry actors, the current draft of the bill does not require the Ministry to do so. The bill should require public consultation throughout the standardization and regulatory processes. Open collaboration with industry experts will help create better solutions for everyone.

Focus the Scope of Certification

We recognize that certification can help ensure that health IT systems meet the same baseline standards. However, it significantly increases the costs of health IT, especially if the scope of the certification is broader than

what is necessary to demonstrate conformance to technical exchange standards. Certification should not mandate prescriptive user interfaces, workflows, or business processes. The draft legislation instead should require certification schemes to focus on conformance to technical content and delivery standards. This will give developers the flexibility to create tools that meet the needs of users while minimizing the cost of supplying certified software, as well as the freedom to explore novel approaches in the future.

The Ministry will also want to carefully evaluate the capacity of certifying bodies. Limited capacity will drive up the cost of certification, and may result in implementation delays. The impact of limited certifier capacity is acutely illustrated by the implementation of the EU Medical Device Regulation, which has seen multiple delays as a result.

Commit to Transparent Processes

The Ministry's supplementary materials state that it intends to adhere to a robust evaluation process before use cases are added to the Roadmap, and eventually regulated. However, the draft bill does not refer to these steps, or refer to requirements that the Ministry must meet before issuing an AMvB for a use case. This reduces the transparency of the Ministry's regulatory processes, and could result in uncertainty for industry actors.

The Ministry should reaffirm its commitment to transparent regulatory processes by including the elements of its intended evaluation process as provisions in the actual draft bill. This will add clarity to the regulatory process for industry actors, and ensure the Ministry is accountable for thoroughly evaluating the costs and benefits before creating new regulatory requirements.

Leverage Internationally Recognized Standards

We support the Ministry's efforts to adopt standards so that providers and developers have a shared understanding of data exchanged across organizations and health IT systems. However, the adoption of Dutch-specific standards will make technology adopted for exchange by the Dutch health ecosystem incompatible with technology adopted by others in the EU and elsewhere. This reduces the portability of Dutch patient data, and could lead to delayed care or even harm for Dutch patients seeking treatment abroad.

The bill should address this problem by requiring the use of internationally recognized and current standards wherever possible. This reduces implementation costs and burden for stakeholders. It also provides enough flexibility to meet any Dutch-specific needs. The MedMij framework took this approach by using HL7's FHIR standard with Dutch profiles where additional specificity was required. It could be further improved by leveraging FHIR R4, which is the current version of the standard, rather than the outdated STU3 Implementation Guide.

Streamline Consent Obligations

The draft bill does not contemplate changes to existing privacy and consent requirements, which could lead to conflicting obligations for providers. Epic is committed to protecting the confidentiality of patient medical data. However, the current opt-in approach to consent in the Netherlands prevents patients and providers from realizing the full benefits of interoperability.

We recommend that the bill include provisions that would allow an opt-out consent model. If the consent model does not change, the Ministry must ensure that it does not restrict the technical exchange standards that can be used by providers to comply with both data protection and data sharing obligations.

DETAILED COMMENTARY
Epic's Feedback on the Draft Wetsvoorstel Elektronische Gegevensuitwisseling in de Zorg

General Provisions (Article 1)

Article 1.1 Definition of Terms

According to the explanatory memorandum, the Ministry intends to regulate data exchanges on its "Roadmap" and create two different "tracks" of regulation. The draft bill could more clearly reflect the Ministry's intent by including those definitions in Article 1.1. We recommend adopting adding the following definitions to the bill.

Roadmap Exchange: A data exchange use case in healthcare that the Ministry has identified as high priority based on industry feedback that the Ministry intends to regulate in the future by designating it as either a Track 1 or Track 2 exchange.

Track 1 Exchange: A Roadmap Exchange for which the Ministry has adopted an AMvB that requires providers to exchange the designated data, but that does not require the use of certified health IT or particular standards.

Track 2 Exchange: A Roadmap Exchange for which the Ministry has adopted an AMvB that requires providers to exchange the designated data using health IT certified to specified NEN norms for that exchange.

Article 1.2 Purpose and Scope of the Law

We strongly agree with the Ministry's assessment that health data exchange improves patient care, and can contribute to reduced administrative burden on healthcare providers. In other jurisdictions in Europe and the United States, we have found that the most effective strategies to increase health information exchange include two elements: (1) focusing government efforts on encouraging the use of standards, and (2) building standards using the expertise of actors across the industry.

We anticipate that adopting a similar strategy in the Netherlands will be effective in creating programs that realize the benefits of interoperability. Our comments throughout this document build on these recommendations by suggesting specific legislative guardrails that will improve actor collaboration with the government, and clarify the responsibilities of actors across the healthcare ecosystem.

Article 1.3 Designation of Data Exchanges and Further Rules

Section 1 (Designation of Exchanges)

According to the explanatory memorandum, Article 1.3 Section 1 is intended to describe the data exchanges that may become "designated" through the adoption of an AMvB. The explanatory memorandum states that data

exchanges on the "Roadmap" are those that will eventually become designated, and describes the high-level criteria that the Ministry will use to determine which exchanges may be added to the Roadmap for future designation.[1]

Promote Transparency Using the Roadmap

The explanatory memorandum states that the Ministry intends to only adopt AMvB for exchanges on the Roadmap. However, the draft bill does not include guardrails that require an exchange to be added to the Roadmap before the Ministry adopts AMvB. This could lead to confusion and uncertainty for industry actors. They will not have insight into whether the Ministry intends to designate additional non-Roadmap exchanges via an AMvB.

The bill should include language that requires the Ministry to place an exchange on the Roadmap before it can adopt an AMvB for it. This will increase transparency. It will also allow for more effective input as the Ministry develops plans to regulate these exchanges.

Section 2 (Tracks of Regulation)

The explanatory memorandum states that Article 1.3 Section 2 describes the rules for the two tracks under which an exchange may be designated under an AMvB. According to the memorandum, an AMvB that designated an exchange as "Track 1" (i.e. an exchange designated pursuant to Article 1.3.2(a) of the bill) would require healthcare providers to perform data exchanges in an electronic manner consistent with specified functional, technical, or organizational requirements. An AMvB that designated an exchange as "Track 2" (i.e. an exchange designated pursuant to Article 1.3.2(b) of the bill) would require healthcare providers to conduct exchange using products or services certified to standards identified in the AMvB for that exchange.

Establish Baseline Requirements for Track 1 Exchanges

On page 14 of the explanatory memo, the Ministry states that Track 1 will require healthcare providers to exchange specified data electronically. It states that Track 1 will not require a specific standard or certified health IT. On page 15, the Ministry states that it may require certain broad functional, technical, or organizational requirements, such as NEN 7510 for Track 1 exchanges. While we think we understand the Ministry's intent, listing such requirements in each individual Track 1 AMvB could result in unclear expectations and delayed adoption.

The bill should direct the Ministry to identify a single set of baseline functional, technical, or organizational requirements that will be applicable to all Track 1 exchanges. A single set of requirements for all Track 1 exchanges will clarify the obligations of healthcare providers and health IT service providers.

Require Adoption of Mature, Consensus-Based Standards

Sections 3.3.1 and 3.3.2 of the memorandum detail the process the Ministry intends to follow to identify or develop standards for Track 2 exchanges. However, the draft bill does not require the Ministry to adhere to this process. This could reduce the number of opportunities for industry actors to collaborate with the Ministry to adopt standards that will best meet the needs of providers.

The bill should require the Ministry to adhere to the process described in the explanatory memorandum. The bill could accomplish this by defining the criteria to which standards adopted in AMvB must adhere. The criteria listed in the bill could align with the elements described in sections 3.3.1 and 3.3.2 of the explanatory memorandum.

[1] Explanatory Memorandum pages 12-13.

The bill should also eliminate costs to participate in the standards process. Doing so will ensure provider organizations and health IT developers can participate. This will improve accountability and drive better outcomes. Industry actors can provide important feedback on functional needs and the technical feasibility of draft standards.

Require Adoption of International or Other Broadly Adopted Standards

We support the Ministry's efforts to adopt standards that align with the specific needs of the Dutch health ecosystem. However, it would be unfortunate if the standards were Dutch-specific, and denied Dutch citizens traveling abroad the ability to share their medical information with other caregivers. Furthermore, the creation of Dutch-specific standards for each Track 2 exchange would increase development costs and implementation burden.

The bill should require the use of international standards for Track 2 data exchanges wherever possible. Industry actors like Epic, other EPD developers, and digital health IT collaboratives like HIMSS and IHE could lend expertise to help the Ministry identify appropriate international equivalents when creating NEN norms.

Leveraging current, internationally recognized standards promotes consistency with other jurisdictions. This would improve data portability for Dutch citizens who travel abroad, as well as visitors from other countries to the Netherlands. It also reduces implementation burden and therefore costs for the health ecosystem.

International standards also allow enough flexibility to meet Dutch-specific needs. Many standards include "core" requirements, but allow locale specific "profiles" to be added to core requirements to meet a specific use case. The Ministry should create Dutch-specific profiles for use with international core standards for Track 2 exchanges.

Healthcare Providers (Article 2)

Article 2.1 Obligations of Healthcare Providers

We recommend that the Ministry solicit feedback directly from providers on the obligations imposed on them by the bill. Robust collaboration with provider organizations will be critical to the success of the proposed regulatory framework, by ensuring that solutions are practical and cost effective.

Transitional Law and Financial Impact Assessment

Section 10.1 of the explanatory memo explains the Ministry's reasoning for not including transitional law in the bill. We agree that a uniform transition period for each exchange would not be appropriate. The Ministry states that it intends to assess appropriate implementation timeframes when it publishes an AMvB. However, flawed assumptions and the lack of an obligation to solicit feedback may result in misinformed decisions.

Part of the Ministry's assessment hinges on an assumption that maintenance provisions in software contracts obligate health IT developers to keep software compliant with applicable laws and regulations.[2] This assumption is not accurate. A blanket obligation for products to meet new regulatory requirements is inefficient and reduces choice for providers. It may be more cost effective to select a different product to comply with a particular regulatory requirement.

During the contracting process, healthcare organizations might ask whether the system they are purchasing complies with specific existing laws. It might also ask whether a process exists to enhance the software to meet

[2] Explanatory memorandum at p.40

known future regulatory requirements. It is not feasible at the point of contracting to anticipate all potential future requirements, nor is it possible to commit regulatory development for a lifetime enterprise system.

Contractually requiring the developer of a particular product or service to meet *any* potential future regulation would be unsustainable for the developer. It would inhibit the developer's ability to effectively allocate resources. Such an arrangement would not be desirable for healthcare providers either. It would needlessly inflate the initial cost of purchasing the product, and increase ongoing maintenance costs. Ultimately, providers benefit from reduced regulatory burden, which potentially results in more choice of health IT solutions.

Information Technology Products or Services (Article 3)

Article 3.1 Certification of Information Technology Products or Services

In Section 3.4 of the explanatory memorandum, the Ministry elaborates on its plan to require the certification of health IT products or services that are used in Track 2 designated exchanges. When an exchange is designated as Track 2, NEN will create a certification scheme that tests the conformance of health IT to the standard adopted for that exchange.

Focus the Scope of Certification

We recognize that certification can help ensure that health IT systems meet certain baseline standards. However, it can significantly increase the costs of health IT. The burden is compounded if the expectations of the certification scheme are ambiguous, poorly defined, or lack a clear connection to the needs of the designated exchange. Broad certification schemes that mandate prescriptive user interfaces, workflows, or business processes stifle innovation. They could force providers to adopt tools that introduce additional burden and do not align with their needs.

The bill should require certification schemes to focus on conformance to technical content and delivery standards. This will strike an effective balance between standardization and innovation. Healthcare providers will have a clear understanding that certified software is able to complete designated exchanges with a common understanding of the data exchanged. Providers and health IT developers will remain free to innovate by designing workflows and user interfaces that best meet the needs of users.

Requiring targeted certification schemes also reduces the cost of supplying certified software. Certifiers would be able to use automated testing tools that validate the content and structure of messages transmitted for designated exchanges. This will be far more efficient than creating complex schemes to assess conformance to prescriptive user interface specifications and will drive down overall costs to the Dutch healthcare system.

Publish Draft Certification Schemes for Public Consultation

We appreciate the Ministry's explanation that NEN would direct the creation of certification schemes for standards adopted for designated exchanges. Similar to our feedback on other elements of the exchange designation process, we recommend that the act require NEN or other bodies developing certification schemes to publish working drafts for public consultation prior to finalization.

Industry consultation on certification schemes will allow health IT developers and other actors to review the proposed certification requirements in depth, and identify items that are ambiguous or confusing. Standards bodies could then leverage that feedback to clarify certification schemes, which would ultimately reduce burden when a scheme takes effect.

Article 3.2 Certifying Organizations

This article defines the requirements for certifying organizations. According to the Ministry's explanation in the accompanying memorandum, market entities will be eligible to apply for accreditation as a certifier, and subsequently administer the certification program. Accredited organizations will be able to administer conformance testing, audit, and surveillance programs for products seeking or maintaining certification.

Evaluate the Capacity of Certifying Bodies

The availability of a sufficient number of entities to issue certificates is critical to the success of a requirement for certification. There must be enough accredited certifiers to meet the demand from health IT developers who will all simultaneously pursue certification on similar timelines to meet compliance deadlines specified in AMvB for designated exchanges. We strongly recommend that the Ministry investigate the capacity of certifiers in the Netherlands before adopting certification requirements to ensure they will be able to manage demand.

An inadequate number of accredited certifiers would drive up the costs of certification, and increase burden on health IT developers as they compete for limited resources. This also impacts healthcare institutions, since a lack of certifiers shortens the implementation time available to them to adopt certified products. Ultimately, this would result in increased uncertainty in the market and deadlines may need to be adjusted due to the low capacity of certifiers.

Article 3.3 Issue of Certificate

We agree with this section.

Article 3.4 Suspending or Withdrawing a Certificate

This section of the bill defines the situations under which a certifying body may suspend or withdraw a vendor's certificate. Our comments are below.

Allow Investigation and Corrective Action

We agree that a certifier should have the authority to suspend or terminate the certificate of a health IT developer if it discovers non-conformance with the requirements of certification during random audits or surveillance activities. However, non-conformities may not always represent willful deviation from the standard. Additionally, not all non-conformities will be of equal significance. Sudden suspension or termination of certificates may disrupt the operations of health care providers. They may suddenly find themselves unable to use a product for designated exchanges.

The bill should require certifiers to follow an investigation and corrective action process before suspending or terminating a certificate. Specifically, following the discovery of non-conformance, the certification body should notify the health IT developer and ask it to investigate the issue in a timely manner. Once the issue is investigated, they should work together to determine a mutually agreeable corrective action plan. If the health IT developer does not satisfactorily mitigate the issue using that process, the certifier can suspend or terminate the certificate.

Article 3.5 Further Rules Regarding Certification

We agree with this section.

Supervision and Enforcement (Article 4)

Article 4.1 Supervision of Compliance

We agree with this section.

Article 4.2 Enforcement of Article 2.1

We defer to the feedback of healthcare providers on this section.

Article 4.3 Enforcement of Article 3.1

We agree with this section, provided that health IT developers are given an opportunity to investigate and correct nonconformities before suspension or termination of a certificate as we describe in Article 3.4. If a health IT developer continues to not comply with expectations of the AMvB after that process, we agree that it is reasonable to assess administrative penalties.

Involvement of Parliament (Article 5)

Article 5.1 Preliminary Scrutiny Procedure

Define a Process and the Requirements to Add Exchanges to the Roadmap

The Ministry states that it intends to add exchanges to the Roadmap based on feedback from actors in the industry and cost-benefit analyses. However, the draft bill does not require the Ministry to adhere to such a process. The oversight mechanism in Article 5.1 also does not require the Ministry to solicit industry feedback.

Health IT developers and provider organizations can provide the Ministry expertise that will ensure exchanges added to the Roadmap are appropriate for regulation. In particular, they can provide detailed information about what data elements are appropriate for inclusion in the designated exchange, the readiness of health IT systems to capture and exchange that data, the availability of technical standards, and the associated provider burden.

The bill should require the Ministry to adhere to a transparent process to add exchanges to the Roadmap. It should also establish guidelines to which the Ministry must adhere as it creates that process. The Ministry's process for adding exchanges to the Roadmap should include the following elements:

1. Publication of an official proposal. The Ministry's process should begin with an official proposal to add an exchange to the Roadmap for designation via an AMvB. The proposal should include the data elements that would be in scope for the exchange, timelines on which the Ministry proposes to subsequently adopt quality standards and NEN Norms in an AMvB, and a complete cost-benefit analysis.

2. Public Consultation Period. A public consultation period should follow publication of the official proposal to allow the industry to provide the Ministry with in-depth feedback on its proposed addition to the Roadmap. The public consultation period will give the industry an opportunity to express support or opposition to the Ministry's proposal. It will also allow them to scrutinize whether the proposed data elements and timelines are appropriate, and whether there are additional costs or benefits the Ministry should consider. Public consultation periods should last at least 60 days, though in our experience, 90 day public consultation periods give actors a better opportunity to give thoughtful and thorough feedback. Actors should have the opportunity to provide feedback in public meetings and through written comments.

3. Reconciliation of Feedback and Final Decision. Following the public consultation period, the Ministry should reconcile the feedback it received and make a final assessment of whether to add the exchange to the Roadmap. If it adds the exchange to the Roadmap, the Ministry should amend its original proposal by adopting revisions that address concerns raised during the public consultation period.

Requiring the Ministry to follow this process to add exchanges to the Roadmap will increase engagement with the industry and build consensus on the optimal approach for such exchange. Increased engagement and industry consensus will improve outcomes.

Consult Actors before Adopting Quality Standards and NEN Norms in a Final AMvB

Similarly, the draft bill does not require the Ministry to consult the industry before it adopts quality standards and an NEN norm in an AMvB that implements an exchange on the Roadmap. As we have emphasized elsewhere in this document, industry actors will be well positioned to provide essential feedback about the readiness of healthcare providers to exchange data according to either track. Allowing actors to review draft quality standards and NEN norms, and provide feedback before requirements are finalized will help ensure that policies are adopted that clearly define technical requirements. It will also ensure adoption of realistic timelines to accomplish the desired outcomes and avoid unintended consequences.

The bill should expressly require the Ministry to incorporate feedback consultations on all components of the draft AMvB before the track of the exchange is officially designated through a final AMvB. We recommend that the bill require the Ministry to adopt a process that includes the same elements described above.

The feedback the Ministry should solicit during the public consultation period on a draft AMvB will be different. In this public consultation period, the Ministry should solicit feedback on the applicability and maturity of standards referenced by the AMvB, and reasonable implementation timeframes.

Require a Transition Period in AMvB

The bill does not require the Ministry to consult industry actors on reasonable implementation timeframes for compliance with an AMvB. Realistic implementation timelines are a critical area of feedback actors can provide the Ministry.

Software developers must be given enough time to develop, test, prepare documentation and training materials, and deploy tools that safely support designated exchanges while meeting the diverse needs of the healthcare community. Healthcare providers must have ample time to implement those tools, adjust their clinical operations, processes, software workflows, and train staff to use those tools to meet the expectations of the AMvB. Rushing implementation increases costs and often requires organizations to repeatedly rework processes, while decreasing the likelihood that solutions meet the needs of users.

The bill should require the Ministry to solicit feedback from industry actors on reasonable implementation timelines for both tracks. The Ministry could solicit that feedback during the draft AMvB public consultation period we recommend above. Then, it should adopt recommended timelines as the transition period in the final AMvB.

Amendment of Other Laws (Article 6)

Article 6.1 Amendment to the Additional Provisions for Processing Personal Data in Healthcare Act

The memorandum explains that the draft legislation would not change existing privacy and consent requirements for exchanging patient data. Therefore, a situation might arise where data exchange is permitted under GDPR and Dutch medical privacy laws, but a patient has not provided consent for the exchange, despite the exchange being required pursuant to this act. This would result in conflicting and ultimately irreconcilable obligations for the healthcare provider, who would be obligated to both execute the designated exchange, and comply with existing consent requirements. To address this, the Ministry suggests that additional technical norms need to be developed to provide alternative mechanisms to complete the designated exchange.

Epic is committed to respecting patient choice in health information exchange and robust privacy protections that prevent disclosures of sensitive patient information to third parties. However, we also strongly agree with the Ministry that increased health information exchange improves care for patients, and enhances the ability for

clinicians to provide safe and effective patient care. Therefore, to ensure that the benefits of exchange are realized without a need to develop additional technical norms, the Ministry should consider including language in the bill that would permit an opt-out consent model for health data exchange.

Opt-out consent models ensure that patients have a meaningful choice to restrict sharing of their data amongst their care team electronically, while reducing burden on providers by allowing easier automation of exchange processes. Privacy protections would not be weakened, since only providers who are part of a patient's care team would have access to sensitive patient information. Health organizations using Epic Care Everywhere in areas that switched from opt-in models to opt-out consent have observed large increases in exchange volume. This ensures providers have the information they need for effective patient care, and ultimately results in better and safer care for the patient.

Other jurisdictions in the European Union have successfully adopted opt-out consent models that are compatible with the GDPR and robust national medical confidentiality rules. For example, Austria has adopted an opt-out health information exchange policy that increases health information exchange while ensuring compliance with GDPR and specifically protecting medical confidentiality.[3] We encourage the Ministry to examine how a similar consent model could be adopted in the Netherlands.

[3] See https://www.elga.gv.at/ for more information.