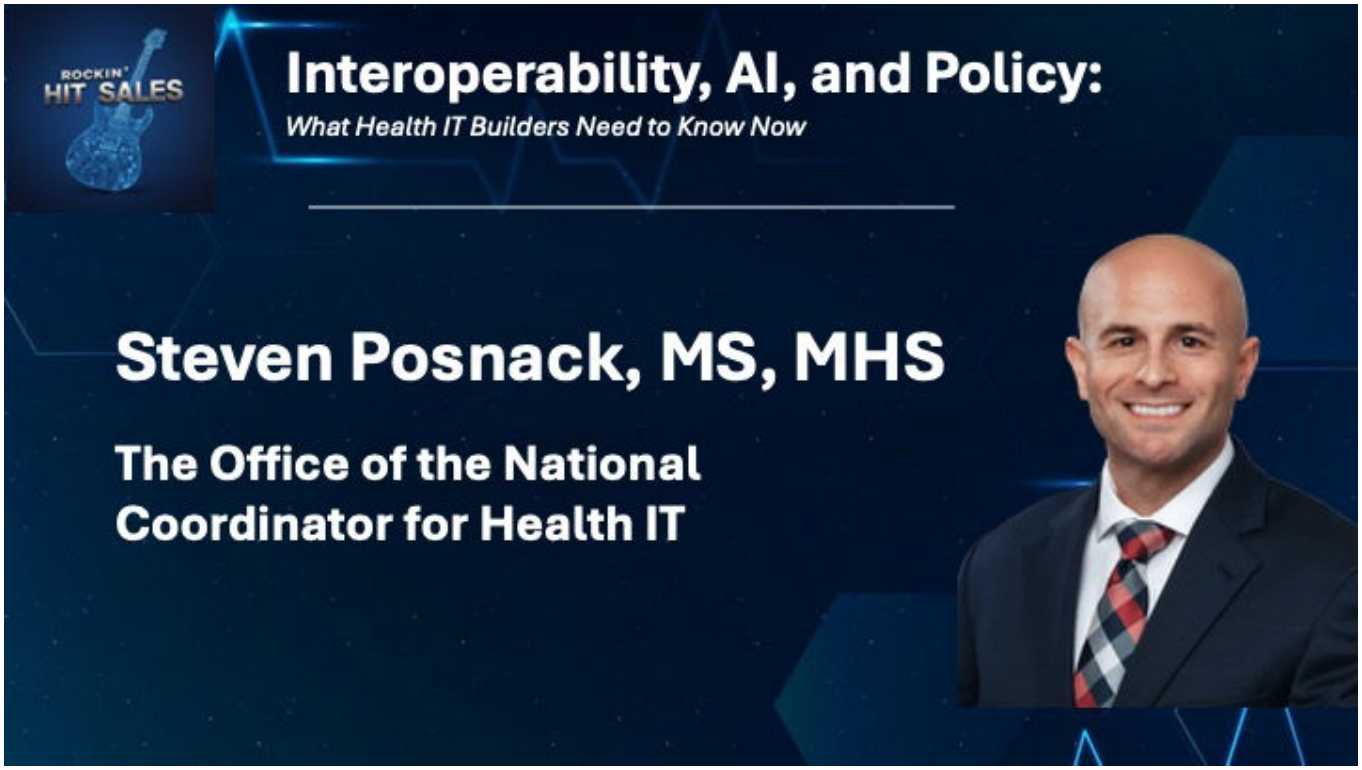

Rockin' HIT Sales

Episode Transcript

Interoperability, AI, and Policy: What Health IT Builders Need to Know Now

Guest: Steven Posnack, MS, MHS, The Office of the National Coordinator for Health IT

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Transcript edited lightly for clarity and readability. Intro and outro omitted.

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David Hacker (00:01)

Steve, thank you so much for joining the Rockin' HIT Sales podcast today.

Steve Posnack (00:09)

Hey, David. I appreciate you asking me to join.

David Hacker (00:12)

Great. Let's start at 30,000 feet. For listeners who don't live and breathe federal organization charts, how do you describe your role at ASTP and ONC and the kind of work your teams focus on?

Steve Posnack (00:27)

Thank you for asking the question. I think the easiest thing for people to keep in mind is this: when you think about health data and how and when it moves, think about us.

To give everyone a brief history, our office, in the grand scheme of the federal government, isn't that old. We're a little over 20 years old. We were created under an executive order from President Bush in 2004. Then, in 2009, the HITECH Act, which was part of the larger Recovery Act, gave us new statutory authorities to administer a health IT certification program. The 21st Century Cures Act in 2016 also updated our statutory responsibilities as a federal agency.

Congress gives us our authorities, and that really drives a lot of the work we do. In the 21st Century Cures Act, which includes many of the efforts people may be more familiar with now, we are advancing interoperability standards, network connectivity through the Trusted Exchange Framework and Common Agreement, and looking at the access, exchange, and use of health information when it comes to what's called information blocking.

David Hacker (01:44)

Thank you for that. As you look across U.S. Health IT right now, what are the big opportunities that keep showing up in your work — things you think the entrepreneurs listening should have in the back of their minds as they build out their roadmaps and products?

Steve Posnack (02:01)

The thing we hear most as we cross paths with entrepreneurs is really data, data, data — and the access, exchange, and use of health data, as I mentioned before. We see it every day now with new AI-related applications. Healthcare is obviously a large part of our economy, and as I mentioned, we have specific authority Congress charged us to implement around information blocking.

That was due in part to Congress seeing anti-competitive practices in healthcare. We still hear a lot of friction from startups and innovators about that, and equally from larger, established companies in highly competitive areas. So as entrepreneurs and investors are out there, they should really focus on the data and how it connects to the work that we do.

David Hacker (02:53)

Many founders think of policy as something that happens far away, inside the Beltway, while they are just out there trying to build and sell their product. Why is it important for early-stage teams to understand the basics of health IT policy and standards, even in the earliest versions of their solutions?

Steve Posnack (03:14)

This is a question near and dear to my heart as a long-time bureaucrat and self-proclaimed health policy wonk. Understanding the policy surround — the intent, the drivers, and what is included or excluded — can help shape untapped opportunities from an entrepreneurial perspective.

It may be a compliance play. It could be a new service or an optimization as policy changes open up different dimensions. As a neutral observation, we have decades of laws that have cascaded into healthcare regulations, and healthcare keeps changing, as we've seen through the use of different modern technologies, including AI. Market opportunities are constantly being created if you are curious and clever. I think that is a real opportunity space in terms of understanding policy and how to apply it.

David Hacker (04:20)

From your perspective, Steve, what are some recurring interoperability pain points where innovative ideas run into real-world constraints around certification, data exchange, and information sharing? And how do you think about using rulemaking to solve these problems — setting the necessary guardrails while still trying to avoid unintentionally hindering innovation?

Steve Posnack (04:45)

As a regulator, I would be on brand to say that I do think there are certain places where rulemaking can help. We have quite a bit of experience now at our office in terms of where things have worked from a regulatory perspective and where things have had unintended consequences. That is one of the dynamics we always have to keep in mind.

At this stage, we are looking at data exchange and connectivity at scale. Those are really important when it comes to advancing nationwide priorities and addressing challenges we face. We're working with industry to advance the Trusted Exchange Framework and Common Agreement — that network-to-network scaling connectivity I talked about earlier.

When it comes to the rulemaking aspect of our work, that happens through our health IT certification program. We happen to be in an interesting rulemaking period where we've issued a deregulatory action to remove a number of certification criteria from our regulatory paradigm as a way to open up more opportunities for innovation, clear out some longer-standing regulatory burden, and focus on the future — especially on more modern, application programming interface, standards-based exchange. I'll try not to use all the government acronyms that I know we torture folks with.

David Hacker (06:04)

Obviously, today there is an explosion of AI and automation across healthcare. When you look at that space from the federal technology policy perspective, what are the key opportunities and the key areas where you want to see some extra care and discipline?

Steve Posnack (06:25)

This is a topic we are acutely focused on and have taken some initial proactive steps around. In December, in collaboration with our Deputy Secretary's office — the executive leadership of the department — we issued an HHS-wide, department-wide request for information on advancing artificial intelligence and accelerating its use in clinical care.

We are trying to get to the bottom of what is impeding the adoption of AI in clinical care. For listeners, they are probably familiar with many components of HHS, including the Food and Drug Administration, Centers for Medicare and Medicaid Services, National Institutes of Health, and ARPA-H for advanced research.

As you look across the department's book of business and the way we operate, we focus on what we call the three Rs. First, there is a regulatory element. A number of agencies across HHS touch AI from a regulatory perspective, and we want to hear from the public and stakeholders in the field about whether there are regulatory changes that would help open up and advance adoption of AI in clinical care.

Second is reimbursement. In healthcare, the financial component is obviously important, so we need to understand where reimbursement changes may need to be considered. Lastly is R&D. We are looking across different components of the department to understand where government investment or government help can accelerate AI use and adoption in clinical care.

David Hacker (08:09)

Many of our listeners are building copilots or decision-support tools. Beyond making sure of pure model accuracy, what else should these organizations be thinking about to build and maintain trust with clinicians, patients, and regulators?

Steve Posnack (08:27)

What we're seeing in the field is a lot of interest from clinicians in adopting these tools, as I mentioned related to our interest in the request for information. They are creating governance councils and other procedural flows to understand what these tools are really about, how these models are trained, and other types of information.

For those building these tools, it is important to understand the clinical context in which they are designed to operate, who is going to use them, and equally, who the decision-makers are in terms of whether those tools get deployed.

David Hacker (09:10)

When early-stage Health IT companies talk with you or your team, what do you find they most often underestimate — either about the complexity of healthcare or the expectations that come with working in such a regulated environment?

Steve Posnack (09:25)

I've heard healthcare is complicated — and perhaps I live and breathe it every day. We have a website, healthit.gov, and I'll also do the public service announcement. The department takes on a considerable

amount of work, relative to our economic impact in the healthcare space. If folks don't have a good sense of who to go to, they can always come to us.

As our name indicates, we are the Office of the National Coordinator for Health IT. We take that coordination responsibility to heart and welcome the opportunity to point people in the right direction and connect them with the right program leads at HHS.

For folks in our space, we also have something called the United States Core Data for Interoperability. This is a baseline set of data that we continue to iterate and standardize for industry. I would say almost take for granted that it is going to be built in from a regulatory perspective as part of our certification requirements and that it is expected for electronic health information exchange. As innovators and entrepreneurs are looking to build products, that is one thing that is very aligned from an industry perspective.

The other resource we have is called the Interoperability Standards Advisory. I like to colloquially describe this as the standardsopedia. If you are familiar with Wikipedia, we have a very geeky version of that. If you are curious about what types of standards are being used for genetic information, behavioral health, or another domain, chances are we probably have some of the standards that we are trying to keep track of and curate in the Interoperability Standards Advisory.

David Hacker (11:24)

If you could design a simple policy and standards readiness checklist for an early- or growth-stage company, what are two, three, or four items you would absolutely make sure were on that checklist?

Steve Posnack (11:40)

Definitely the HIPAA rules. Hopefully folks are very familiar with knowing whether they are going to be operating in that environment and need to follow HIPAA policies and procedures, data protection, and so on. Equally, if they are not operating in that environment, they need to understand whether they may have to comply with different state laws, which may also be applicable, or Federal Trade Commission requirements. Those factors often come up, especially if you are doing a direct consumer or patient-oriented service or application.

On the standards side, at the data level, understanding the different data standards that are available is important. We typically refer to those as semantic data standards — understanding how data is computably represented.

Equally, if folks are using different types of connectivity and data exchange modalities, the one that is most popular right now from a health standards perspective is HL7 FHIR. But we are also seeing, with different AI agents and other tools, expansion in different types of connectivity in the healthcare space.

David Hacker (12:55)

Some founders feel like federal standards or certification are things that only the 800-pound gorillas in the digital health room can influence. Is there a realistic way for smaller, newer organizations to get involved and stay engaged without it consuming all their time, because they do have their day jobs?

Steve Posnack (13:18)

Absolutely. That is why I would highlight the deregulatory action we recently put out. It is available for public comment until the end of February, so folks still have time. That signaled to industry that we were ready to turn the page and move in a direction that was very much application programming interface focused and interoperability focused.

We hope it will encourage additional entrepreneurship and innovation in the electronic health record space. By reducing the amount of certification criteria as we proposed, we think that will be a way — and hope it will help — make it easier for the broader community to follow along and provide input.

David Hacker (14:11)

Now we're into our lightning wrap, our final two questions. The first question you already answered, but I'll ask if there is any more detail. If someone is starting up a Health IT company today, what is one publicly available

resource or initiative from your team that you would encourage them to bookmark and keep coming back to? You already mentioned healthit.gov. Is there anything else that is the best place for them to start and stay in tune?

Steve Posnack (14:38)

Healthit.gov is definitely the big front door. The bonus item I would add is that they can sign up for our listserv. We try every week to send out updates, and that is another way to stay in touch and keep tabs on what is going on.

David Hacker (14:53)

My final question for you, Steve, is this: what is one question you wish every founder would ask themselves before they start building and deploying a new digital tool into the clinical environment?

Steve Posnack (15:07)

I think this is probably a three-part question to answer. I assume this aligns with how most founders think, but I would anchor it to: what is the problem I'm trying to solve? Is this effort that I'm leading making a real issue better for people? And lastly, what is my pathway to scale that impact to as many lives as possible?

David Hacker (15:41)

Steve, thank you so much for taking the time to join Rockin' HIT Sales and for walking us through how policy, standards, and innovation all really do fit together. This is exactly the kind of information and perspective our audience needs as they are building, scaling, and selling their products.

Steve Posnack (16:01)

Thanks for having me, David.