

Community Review – RIAPCD Proposed Regulations

February 27, 2012

1:00 RI Department of Health Auditorium

Attendance: Mary Poulin, Chris Marino, Steve DeToy, Phil Anderson, Darby Buroker, Rosa Baier, Stefan Gravenstein, Richard Glucksman, Mike Souza, Mary Evans, Steve Brown, Jay Buechner, Patrick Ross, Stephanie Deabree, Rachel Schwartz, Lucy Maddock, Jennifer Wood, Lindsay McAllister, Bill Dundulis, Tricia Leddy, Melinda Thomas.

COMMENTS

INTRODUCTION

1. Melinda Thomas provided a context for today's meeting: created in 2008 but was not funded. ACA passed and money became available under aegis of rate review. Private health insurers, enrollees, exchange, Medicare and Medicaid will report all claims to HEALTH or designated vendor. The regs were prepared by gov't staff based on CO, VT, MA, ME and national guidance from the national APCD Council.
2. Tricia Leddy added that part of the exchange requirements includes balancing some funds in the individual and commercial insurance market: RRR's (reinsurance, risk adjustment and risk corridors). This balances some of the risk that will result from the fact that all people, regardless of health status, will be enrolled with similar rates instead of different as they are now. This will address that potential unbalanced risk across insurers. In order to do this, we need to have a risk adjustment member and claims file and an APCD, under the federal proposed rules, to provide the data to make these potential cross-insurers payments to balance this risk. The deadline for using this for the 3 R's is that it must be "operational" by Jan 1, 2013. This is the same date that Insurance Exchanges on the state level must go "live."
3. Melinda Thomas continued and explained that there are 2 parallel processes going on here: the regulations, which must meet regulatory steps along the way; and the purchasing/procurement process. We've selected a vendor for the aggregator and one for project management. The regulations will be revised after today, then posted for public hearing.

We're hoping that the aggregator vendor can begin in May and start working with the payers on the data submission guide. We also hope to finalize the guide by June, then

have the health plans program their systems to work with the aggregator by September. Testing will begin Sept./October, and then receive historical files by Nov./Dec.

4. This meeting is not a public hearing – it's meant to be an exchange and the State would like input. The comments will be posted on the website.

PUBLIC COMMENTS:

- Mary Poulin from Tufts – We've just been through the process in Massachusetts and it was very painful. This was partly due to the complexity of what the state asked them to provide. So far, the document that has been provided in RI looks much more simple and straightforward. Conversely, MA asked for data that was heavily inter-related. They wanted relationships among payers and dependencies between the files. We ask that in RI, the approach reflected thus far be maintained.

- Steven Brown ACLU – You mentioned the contract was being finalized, but the proposed regulations don't really address whether there are confidentiality requirements for the vendor. Tricia Leddy: all vendors sign legal confidentiality agreements.

- Steve Brown -- if there's a breach, is there anything in the contract that addresses how that would be approached?
- Tricia Leddy: there are clauses in the contracts, especially when using PHI, and that would be something that we'll pay close attention to.
- Steve Brown: it sounds like the signing is imminent, so...
- Tricia Leddy: there is plenty of time for this because the signing of the contract with the vendor has not yet occurred. That is a great comment.
- Steve Brown: will there be an opportunity for minor word changes – we don't need to go over these here – so will there be an opportunity to address these over the next week? We could do written testimony?
- Tricia Leddy: one week. We're trying to speed up.
- Steve Brown: Has there been any consideration in other states to allow patients to opt out of having their information provided?
- Tricia Leddy: haven't heard of anything like that because the person's information is not identified. Haven't heard that that has been an issue.
- Bill Dundulis: you can scan the letter in and send to me or Melinda and then the hard copy can follow whenever.

- Steve DeToy: on health information; will this include all history like labs and xray?

- Tricia Leddy: it won't include clinical results, just that it occurred.
- Steve DeToy: how about treatment? Is it what happened or what was paid for?
- Tricia Leddy: what was paid for.
- Bill Dundulis: there is a standardized coding usually used that providers submit to the health insurers indicating whatever the appropriate diagnosis or treatment was.
- Steve DeToy: not exactly because this is *paid* claims and not submitted claims and its important to keep that in mind.
- Tricia Leddy: can't remember whether this has billed/denied/paid distinction.
- Mary Poulin: episode grouper?
- Tricia Leddy: I'm not sure –
- Mary Poulin: MA has fully denied claims.
- Tricia Leddy: MA has done this a bit differently, I'd compare what we're doing with TN, CO, MN, and other states that have similar systems which follow the national APCD model such as VT, ME and NH.
- Bill Dundulis: We looked at the MA enabling statute and their statute is totally different. Our statute is more similar to VT. Some of the things MA did we couldn't ask for because of the way our statute was written. MA had a different definition, for example, of de-identified data.
- Tricia Leddy: some technical questions can be addressed by the technical submissions guides which we're hoping to finish by June. Other states have finished theirs so we could tell you where to go for those if you're interested.
- Lucy Maddock: Discrepancy between healthcare claims data and 1.19 and medical claims filed. The earlier definition suggests a database with information consisting of all medical claims so why is it being limited to all being paid rather than submitted.
- Tricia Leddy: I think I misspoke and its what was submitted and what was paid. There are two transactions, each numbered, and one is what the provider sends to the plan and what the plan sends back to the provider and what is collected includes information from both of those transactions with specific.
- Lucy Maddock: I'd want to see what information is being used when talking about the data sets – what definition is being used.
- Tricia Leddy: the healthcare claims definition or the medical claims file – I see.
- Unknown commenter: --Because that determines what the insurer is deciding to submit. "Service level remittance" is probably a misnomer – we could correct that and put submission "charge," for example. Bill: we could check it against the national wording, for example, VT.
- Tricia Leddy: Logically, it sounds like the medical claims says remittance and includes both info from the claim going both ways to the provider and back from the insurer.

- Steve Brown: indirect personal identifier; this information or with other information can id someone. It seems that if there is one piece of information alone which could id someone, it should be considered an identifier.
- Tricia Leddy: it sounds like the identifier name...
- Bill: Dundulis we'll double-check it, it's a good point.
- Tricia Leddy: we'll see where we're using it in the regs to make sure we're using it in the right way.
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- Steve DeToy: Discrepancy with 1.27 and 1.28 and going back to the appendix and I'm confused by how the chart works. Analytic restricted release: the things on the back in the appendix –
- Melinda Thomas: the 1.28 should be A. It should be A in both.
- Steve DeToy: what does “yes” mean – why are they all yes?
- Tricia Leddy: that's what the plan sends in the database. Then the prior columns say –
- Steve DeToy: that gets to the submitted versus paid – is it
- Tricia Leddy: A is the information about the member enrolled in insurance and the claims file is the claims submitted and paid so the provider sends a request for payment with what treatment was provided to the plan and the plan says what it'll pay for, sending it back to the provider. All that information goes into the health plan database, which then takes the elements that are part of that transaction and provides the elements listed on page A2, to the APCD. The claims information starts on middle of A2 and continues on A3 – that is the information about the plan.
- Mary Poulin: the restricted use is what the researchers might use later?
- Tricia Leddy: yes. It depends on the cell size. There are some restrictions about the cell size being used. Some restrictions to make sure the data isn't identifiable even at the service level – the public use column – this is open for comment – would be available. The restricted use column would go through data review committee the department would establish to give information to some of these elements if they need it for a very specific purpose. This is like IRB.
- Steve DeToy: that isn't clearly defined under restricted release analytical files. It doesn't say for what use and how they are restricted and if a physician wanted access, and its under the restricted use file, does the doctor have to go through the committee just to get their own information?
- Tricia Leddy: the doc could get information about their claims files, but not the restricted data elements. This is very different than the Health Information Exchange that the RIQI is developing – in that that does have identified people and their health information, including clinical information, intended to be used by physicians on a personal level for case management. This is not intended for that use. The physician would not be able to get identifiable information under this system. They cannot find out how their practice is doing – get a list of patients, for example – this is not for that purpose.

- Steve DeToy: the curiosity to see how their practice is doing, they'll have to go through this process to get access to their own information – it seems onerous.
- Tricia Leddy: it seems that the service provider is able to be identified. We're using a list that the other states have used in the recent past and asking for comments. It looks like for public use, you might be able to get service provider last name or organization name and if you went to the IRB level, you could get all the information about the service provider. We're very open to suggestions in this process.
- Steve DeToy: is there a definition of how the department will make that determination under restricted use?
- Bill Dundulis: 7.4, page 9.
- Steve DeToy: I suggest that in the open meeting that if the provider wants data that is in the restricted use column, this is pretty onerous. If they want to research how their own practice is doing and its created by the work they're doing, they should be able to do that.
- Tricia Leddy: so they should be able to get their own data, without identifying data.
- Steve DeToy: they should have ability to look at their own.
- Stephanie Deabree: that's physicians or facilities? And organizations as well as the physician providers.
- Tricia Leddy: Good suggestions, this is the process we're going to go through as we get suggestions – look and see if we can find pro/con information, especially focusing on confidentiality of patients.
- Mary Poulin: data won't be that helpful without benchmarks so it might be smart to publish benchmark data.
- Tricia Leddy: Good point. We have a plan this year to create an analytic plan and put out aggregated data on the DOH website so that people can use the data without being a researcher. The aggregate, or rolled up data, will be more useful to people such as physician practices. I'm not saying we're going to publish data for each practice because depending on the size, it might not be useful. We need to do this in a size that is meaningful – so a lot of data would be more meaningful if done by practice rather than physician level. We'll be looking to make sure we're not mis-using it by skewing it due to the sample size.
- Rachel Schwartz: I want to suggest something in terms of the overview – you should know what the key analytical questions are before deciding on the data. For example, I don't know if doing it by practice is part of the data request. I urge you to determine your 20 questions, for example, before asking folks to put together files. With regard to 2.3 "exemptions" did anyone estimate how many lives would be excluded as a result of this exemption?
- Tricia Leddy: it was well-below 50,000, but I cannot remember how many total lives, but it was not as many as I thought.
- Rachel Schwartz: do you think its around 5% of RI population?
- Tricia Leddy: that could be right. I got my information from OHIC. National Insurers have some numbers on this.

- Bill: I believe subparagraph (b), I believe those particular categories were exempted by statute.
- Steve DeToy: you have 17-17 and it should be 17.17 in 1.29.
- Darby Buroker with RIQI: observation about 2.2 and 2.3 the keys are to maintain the deidentification, and it appears you do, but the issue may be operational – you’ll want to do this plan to plan – so that as they move, you’ll know that even though they’re deidentified. Also, execute this in a way that you’re open to linking to other patient deidentified sets so you can match those data sets. Again, this would all be part of how you manage the third party vendor to do that deidentification. You would want one vendor that is able to coordinate across these datasets.
- Mary Poulin: clarification, if a RI resident works in MA and gets care in MA and is covered by MA contract, you still want it? That is tricky.
 - Tricia Leddy: because you’re a cross-border plan?
- Mary Poulin: yes.
 - Tricia Leddy: whether the healthcare was provided outside of RI – if they work in MA and therefore their employer-provided healthcare is provided in MA...
 - Tricia Leddy: I don’t think that the APCD included that.
- Mary Poulin: so it would be a RI business.
 - Tricia Leddy: I’m pretty sure the national definition, which we’re trying to follow is that RI is the RI book of business of an insurance company for RI residents, regardless of where they get their care.
- Mary Poulin: so they go to AL and break their leg – its still part of the RI book of business. Could you make that more clear?
 - Tricia Leddy: that is what the technical manual will provide. This will include the details about how to submit the data, the encryption, what to include and what not to include. Every time you have a little change to a technical piece, we don’t want to have to go through the regulations so we’re trying to keep the policy in the regulations and the technical decisions in the manual.
- Rachel Schwartz: With respect, I thought that was a conceptual question not a policy question. If they have over 3,000 lives it doesn’t matter if they’re across the border. So someone with factory across the border with RI residents, -- if they have more than 3,000 residents, it doesn’t matter ...
 - Tricia Leddy: it depends on what part of the company is licensed in RI. We’ll ask OHIC for clarification on this. Does RI authority extend to MA in that case?
- Steve DeToy: you’ll have physicians submitting claims data and you’ll only get it from the insurers side. You’re going to get the data from all their patients unless they exempt, those that got their care within the state. You’ll end up with people who are providing care here, but –

- Tricia Leddy: what we need to do is define it as clearly as people are asking. The residency of the member, a definition of the jurisdiction of the health plan book of business that will be included in the APCD and we will consult OHIC on that and the provider – whether they’re in or outside the state. We need to define the book of business we’re regulating more clearly.
- Steve Brown: 1.4(c) the web-based system – we want more standards there. There are various levels of secure web systems and we’re concerned that something to key to securing data is left so open-ended.
- Tricia Leddy: we can certainly look at that.
- Bill Dundulis: you have to walk a fine line between setting a standard that will be obsolete by next year. When we did the health IT regulations, there were some minimum standards and we can look at that.
- Tricia Leddy: conform the standards with some entity.
- Lucy Maddock: 4.3, “Data files to be submitted” – the definition is the narrower definition that suggests payers only have to submit what they’re paying for rather than all claims received.
- Tricia Leddy: excellent point. We should use the earlier definition of healthcare claims.
- Chris Marino with Tufts: with regard to milestone that the submissions are tied to, they should really be tied to technical specs slated for June because that is what we’ll need to deliver the files. If the regs are issued and the technical spec is delayed, we can’t make up that time.
- Tricia Leddy: I see that. We’re just trying to get the specs out when the regulations are filed.
- Chris Marino: I have concerns about that, especially with testing. You’re going to want at least 2 months for that timing. 32 days is not enough time. I really think it’s a 6 month effort 120-180 is realistic.
- Tricia Leddy: we’re trying to make the Jan 1st operational deadline.
- Chris Marino: so tie to that. In MA, something that was late was the exact list of edits. For every field, cannot be zero, for example. That has to be in the specs if you hope to make this date.
- Tricia Leddy: so we need to include the edits we’re going to use to perfect a submission?
- Chris Marino: yes.
- Jay Buechner: how did the dates of July 1 and Oct. 1 tie into the schedule? That will be before we run a test file?
- Bill Dundulis: That was probably overly optimistic from an earlier draft that we didn’t catch.
- Steve Brown: Regarding section 7: I want to make clear in terms of the data use request documentation – at this level, my understanding is that there’s no personally identifiable information that is accessible, like other demographic information, but the appendix B with

the flow chart talks about unusual / restricted requests and mentions personally identifying data. This needs to change. Also, the process of 7.4 for determining whether and how types should be released, but US SC decision dealing with VT's pharmaceutical data act – and there were first amendment issues with restricting entities from obtaining the info in that database because it allowed certain entities to get it and didn't allow it to others to use for marketing purposes. Want to make sure the restrictions in place won't be able to challenge them for restrictions on first amendment rights.

- Steve DeToy: the companies were using the data to market as to prescriptive habits and the court said there was free speech access rights to that.
- Jennifer Wood: we have looked at that case and believe we're on firm footing. We want to make sure we're being cautious about that, and will take a close look at it.
- Stephanie Deabree: We're curious about how far reaching the analysis will go back to the Board – prior to release, the data request has to be reported back to the review board. Is that every time? If it's not in the data use agreement, we'd have to go back to the Board? This needs to be more specific – which times do we need to go back to the IRB? Once we have the specific use approved, maybe we shouldn't have to go back to the IRB?
 - Tricia Leddy: we'll look at this. We'll have to look at other examples of where this is written.
- Steve Brown: on this, there may be some significant first amendment problems – once you determine this data is useable by an entity, the ability to require a review of any report first might be limited.
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- Steve DeToy: data release review board – is that what you're calling the IRB?
 - Tricia Leddy: yes.
- Steve DeToy: where do we find that?
 - Tricia Leddy: its in the department. The DOH is the owner of the data and is responsible to make sure that no identifiable information is release. The DOH is the keeper of the data so must make sure releases are appropriate.
- Steve DeToy: that is fine and great, but who are they and where do they exist? How is the IRB composed and comprised?
- Jennifer Wood: The definitions section fleshing this out.
- Jay Buechner: the way these procedures are worded, they refer to public use and restricted data set – it's not always clear in 7.4 that you're referring to restricted use. The review committee should have reps from the health plans. Are you planning to get FFS from Medicare and Medicaid and managed care too?
 - Tricia Leddy: commercial self and fully insured, Medicare managed care and Medicaid managed care from the health plans and Medicare, FFS from Medicaid . The only one we're still working on is Medicare FFS. They have 2 files and we don't know which one we'll be able to include.

- Jay Buechner: there's a set of fees for receiving these data if you request them and I'd ask that you consider waiving for entities that submit data given that they've undergone a burden just submitting the data.
- Rich Glucksman with BCBSRI: We're preparing written comments that we'll submit within the week. Modeling the review board after other states is a good idea. Planning this entire thing, there's a reference in the statute to a steering committee. We appreciate the opportunity to participate and would want to remain involved in the steering committee cases. Steve and Jennifer brought up good points about the severability clause – if parts are invalid it wouldn't effect the entire bill – if you lose important protections, would you still want to move forward on the remainder of the bill?
 - Bill Dundulis: All of Appendix A and B we'll take together:
- Mary Poulin: second the comment about having a list of desired analytical questions from the outset because there are many elements that MA has that are not here so you'd want to avoid a scramble to get them in at the last minute.
- Jay Buechner: public use data files. What does the "if needed" mean? Would there be several versions of the public release?
 - Tricia Leddy: the standard gives people about 95% of what they need and there's another version where you could get the rest. Maybe we should say "if requested" which might be clearer.
- Rachel Schwartz: linking? An analytical question could come up that isn't linkable – it should be within the construct of what you're trying to do.
 - Tricia Leddy: even so, everyone who might use the public data file might not have access to that other data set.
- Rachel Schwartz: I don't think you're asking if a person died or not. I think there are a lot of things that aren't in here that you're not intending to link to.
 - Tricia Leddy: somewhere in the member file, this doesn't have the definitions and spaces, but somewhere there is a requirement for a start date and end date – but I don't see reason.. That's a good point. What is the reason for disenrollment.
- Rich Glucksman: adding things will be problematic so it's important to imagine what you're going to be asking. Also, you've thought a lot about identifiable and not – if you propose linking the identifier number to other data sets – you run the risk of identifying data you worked hard not to identify. Especially in a state as small as RI.
 - Tricia Leddy: we've thought about that issue and the way we've thought about that is that our system wouldn't preclude linking, but we are not, right now, setting up to link with other databases.
- Rachel Schwartz: the reason I said this is that on page i – linking cancer patients, congestive heart failure patients – think about what you're trying to do. If you don't know the outcome, you don't know how to improve outcome.

- Lucy Maddock: this information is deidentified from a patient point of view because with the zip codes, especially in specialties, its easy to work backwards. This levels the playing field in terms of the insurance companies. This means you're not aggregating.
 - Tricia Leddy: we've always had insurer level data but not at a practice level. This is aggregating data at a practice level, but not at a member level. We're not planning to link at an individual level. We're being very careful about the identification of people.
- Mary Poulin: will there be opportunities to participate in the technical manual?
 - Tricia Leddy: yes. As soon at the vendor has seen approved we will schedule those.
- Stephanie Deabree: would it make sense to have someone from VT who has been through this process available to answer these questions?
 - Tricia Leddy: at the public hearing?
- Stephanie Deabree: If not, then maybe review their public comments and see how some of these questions were dealt with. MA had webinars, workshops, open dialogue and that assisted people who would later be submitting as well as using that data.
 - Tricia Leddy: we want to have that sort of open dialogue. We can try to have more open meetings and perhaps do another informational meeting to answer some questions and have someone who has been through the process before available to help answer questions.