Healthcare Regulatory Round-Up #81 Webinar Transcript

340B Update: Where We Are and Where We're Headed

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SPEAKERS

Sarah Bowman, PYA Moderator

SUMMARY KEYWORDS

340B Program, 340B update, legislative activities, regulatory update, patient definition, drug manufacturer restrictions, Medicare Advantage, HRSA audit, contract pharmacy, child site, compliance, transparency, reporting requirements, litigation, compliance strategies, program benefits, audit findings, 340B Patients Act, 340B Access Act, 340B Sustain Act, Genesis Case, covered entities

WEBINAR SUMMARY

Sarah Bowman discussed the 340B program's legislative and regulatory updates, emphasizing the two schools of thought on program reform. She highlighted the House Energy and Commerce Committee's consideration of the 340B Patients Act and the 340B Access Act, which propose varying levels of restrictions and transparency. She also addressed drug manufacturer restrictions, the revamped administrative dispute resolution process, and the impact on contract pharmacy arrangements. She mentioned the Genesis case, which challenged HRSA's patient definition, and the ongoing litigation related to contract pharmacy restrictions. Additionally, she covered Medicare Advantage considerations and HRSA audit activities, noting common findings such as diversion, duplicate discounts, and incorrect Office of Public Affairs and Consumer Education (OPACE) records.

ACTION ITEMS

- ☐ Review and update 340B program policies and procedures to ensure compliance.
- ☐ Audit internal 340B program oversight and documentation to be prepared for potential HRSA audits.
- ☐ Evaluate the impact of 340B reimbursement reductions on Medicare Advantage claims and pursue adjustments with payers.
- ☐ Stay informed on legislative and regulatory changes to the 340B program and adjust program operations accordingly.
- ☐ Consider pursuing the ADR process if facing significant contract pharmacy restrictions and document the financial impact.

TRANSCRIPT

PYA Moderator **00:02**

Thank you for joining us. The webinar will begin shortly.

Good morning everyone. Welcome to the latest episode of PYA is Healthcare Regulatory Roundup webinar series. Today's topic is 340B Update Where We Are and Where We're Headed. PYA is happy to present today's webinar on this important topic.

You may submit questions during the webinar by typing a message into the questions pane of the control panel. Also immediately following the end of the webinar, you'll be asked to complete a short survey and submit any additional questions, we'll respond to questions posed after the webinar via email. We've posted in the handouts pane of the control panel a PDF copy of the slides for your reference. Also, you'll receive an email later today with a copy of the slides and a recording of the webinar.

With that, I would like to introduce our presenter, Sarah Bowman.

Sarah Bowman **01:23**

Good afternoon, and thanks for joining today's Healthcare Regulatory Roundup. Today we'll be discussing 340B. My name is Sarah Bowman, and I'm excited to be with you today discussing this important topic on how providers such as yourselves can maintain a compliant environment and stay informed about the latest challenges and updates that are happening in this space.

Today's presentation, we're going to cover a number of areas. We're going to try and go quickly to be efficient with your time. We're going to go through federal and state legislative activities as well as a regulatory update. We will discuss the recent activity surrounding patient definition, we will discuss drug manufacturer restrictions and the revamped administrative dispute resolution process, which changed earlier this year. And we will discuss Medicare Advantage considerations, particularly those related to 340B acquired drugs and some litigation that's occurring in that space. And then we're going to wrap with a discussion on HRSA audit activity and additional program considerations for covered entities in today's somewhat challenging 340B environment. So, with that, let's get started.

2024 has certainly been an eventful year for healthcare, for politics. There are a number of healthcare programs out there, including 340B, that have been targets. They've become targeted and challenged in this space. So, it's not surprising that we are seeing several pieces of, excuse me, several pieces of legislation proposed to change 340B. As a very quick history lesson, the 340B program was enacted in 1992 with the intent to stretch scarce federal resources as far as possible to reach more eligible patients and provide more comprehensive services.

So, today, we really have two schools of thought when it comes to the 340B program. So, one is the program is operating the way that it was designed. You've got covered entities that are participating. They are able to provide more benefits to their communities, offer services, you know, have certain clinics open, you know, flu shot vaccines, think things like that they're able to do because of the 340B program. So, it's operating as designed. Cost taxpayers nothing. We need to protect it and maintain it. That's sort of one

school of thought. The other school of thought is, gosh, there's not been a whole lot of change to the program since the 90s. There aren't a whole lot of black and white guard rails or parameters in the program. We need to change that. We need to maybe tighten up some definitions. We need to add some perhaps some restrictions, some rules. We need to make sure that we understand how cover entities are using these savings that they're getting.

So, the 340B program requires drug manufacturers that participate to offer discounts, offer significant discounts to drugs that are required under the 340B program. Obviously, every provider out there in the country cannot participate in 340B. You've got to meet certain criteria, depending on your entity type, your provider type, for a lot of hospitals in the United States, that means meeting a particular dish threshold, disproportionate share threshold of patients.

So, there are a number of bills. It's not surprising that there are a number of bills that are being put forward to potentially do just that. Add some guard rails. Add some structure. Add some. Conversation. And again, you've got kind of both, both sides thinking about, how should we do this? How can we do this? I mentioned those two schools of thought. That's really what I mean when I say both sides. You've got people that are in the camp of, let's maintain the program. It should stay, for the most part, similar to how it exists today. They're looking to add guardrails, add parameters, add definitions that help support the program, but that don't limit access or are not overly burdensome from an administrative perspective for any of the covered entities that participate. Then the other school of thought that's saying, you know, we want to understand more about what's happening to the program. We want some reporting. We want transparency. So, the bills that I'm going to run through have both of those schools of thought in mind, although some are more provider-friendly than others.

So, the House Energy and Commerce Committee is considering two separate partisan 340B reform bills right now. One is the 340B Patients Act. The other is the 340B Access Act, which I'll discuss in a moment.

The pharmaceutical access to invest in essential, needed treatments and support act of 2024, or 340B Patients. Act, it's a mouthful, was introduced back in March by Representative Doris Matt Sue from California, was co-sponsored by nine House Democrats, and would prevent drug makers from restricting covered entity contract pharmacy use. It would also levy civil monetary funds on manufacturers for violations, so it would make sure that they have some skin in the game too. It is supported by a number of provider industry organizations, including the American Hospital Association, the Association of American Medical Colleges, and the National Rural Health Association, as well as 340B health. And it has gotten some additional traction in September, so just last month, Senator Peter Welch introduced the Senate version of the 340 Patients Act. So, we'll see how that how that plays out.

The 340B Access Act or affording care for communities and ensuring a strong safety net. Act. It was introduced in May by Representative Larry Bucha from Indiana, along with two other ANC Republicans from Georgia and my home state of Tennessee. This bill would limit 340B hospital eligibility. It would increase reporting requirements and restrict the use of savings on covered entities. So, it adds some restrictions there in terms of how they're how covered entities are using the savings that they gain from the free four to be program. It would also codify certain uses of contract pharmacies, among a whole host of other changes, we define the covered entity patient, which has been a subject of much debate that we'll talk about here in just a moment, it would establish child eligibility, and then it would require covered

entities to use a sliding fee scale for drug discounts to pass those on to patients. You might be listening to this and thinking, well, that sounds that all sounds okay on paper, there are a number of organizations, including the American Hospital Association, that are really concerned about some of the more stringent terms and parameters that are included in this proposed bill. In fact, the AJ submitted a letter earlier this summer expressing some concerns about the impact to existing covered entity providers if this were to go forward and the narrow patient definition some of the eligibility parameters would tighten. The American Hospital Association actually estimated that about 75% of urban dish hospitals could be impacted, negatively impacted, in terms of their ability to access 340B in the future if this moved forward.

There's also the 340B Sustain Act. So, the Sustain Act was brought forth by a bipartisan group that had actually put this together. Requested information from both 340B stakeholders, as well as drug manufacturers, and both sides responded with a number of comments. Generally, many of the components were agreeable for provider organizations and favorable. That was definitely reflected in the comments received. There were also some disagreements about the key components, concerning the 340B patient definition and the requirements on spending 340B savings.

Over the summer, additional bills were introduced that would designate rural emergency hospitals so our EHS as 340Be covered entities, allowing them to also take part in the program. And there were also bills that would extend eligibility to disproportionate share hospitals that are operating and physically located in US territories, allowing them to qualify and participate in the program as well. So, again, we continue to see a whole lot of activity in this space.

So, these bills, along with others, will continue to focus on putting some definitions in place, putting some parameters in place, increased transparency, and reporting, and then potentially requiring. Some additional auditing, or a minimum, some reporting of how covered entities are using their savings. So, it's definitely fair to say that there has been and continues to be a lot of activity in this space. Whether these things will ultimately impact the way the program operates in 2025 or in the near future, remains to be seen, in addition to the federal level, regulatory and legislative activity that we see going on, there has been plenty of activity on from a state level as well. So, the restrictions that are being imposed by various pharmaceutical companies, paired with some of the concern about lack of black and white guidelines and definitions within the program, and leaving a lot of things up for interpretation has caused a lot of states to take matters into their own hands and craft their own laws around 340B requirements for their states. In addition, there are states that are putting forth proposed actions to help support covered entities in their states not have to be subject to the restrictions from contract pharmacy, excuse me, from drug manufacturers on contract pharmacy drugs.

So, in right now, you've got drug manufacturers that are restricting access to medications across the country, this is happening, and so you've got pockets of states, specifically the states that are pinned on this map, that are taking those matters into their own hands, trying to fight back and say that's not something that is going to be permitted. Pharma has responded. And there are a number of litigation cases out there that are active surrounding this. This challenge of how do we handle contract pharmacies was, were contract pharmacy dispensations, something that was even contemplated when the 340B program was enacted to begin with, and so you've got some folks that say yes, some folks that say no. The reality is, most covered entities have contract pharmacy relationships are expecting to be able to leverage those contract pharmacy dispensations as part of their program and receive those discounts.

So, again, be aware of what's happening in your state, it can certainly impact your program as you're thinking about your policies and procedures, your operations, things that you might need to do related to reporting. Sorry, I jumped ahead on my slides. There are things that you might need to be doing from a reporting perspective, definitely, definitely be aware of what's happening in your state.

So, talked a little bit, I mentioned about patient definition being something that is definitely from a regulatory perspective, from a legislative perspective, it's being challenged. It's being brought forth as, gosh, we can't even agree this, this patient definition is, is very gray. And so that is something that is at the, at the at the heart of most of the legislative activity that we are seeing, maybe not all but, but certainly a lot of it. So, it's one of the many gray areas of the three, four dB regulation as it exists today. It really hasn't changed much from the way that HRSA defined it 25 years ago. There are, there has since been some, some interpretations that we will talk about in a second with the with the Genesis case, but, but for the most part, a lot really hasn't changed in the 25 years or so that the 340B regulation and patient definition guidelines have been out. So, those guidelines state that all covered entities must establish a relationship with their patients such that the entity will remain responsible, responsible for their care, and maintain records at the individual's health care and then it goes on to say that an individual is not considered a patient of a covered entity, if the only care that's being provided is the dispensing of drugs, whether that is for self-administration or administration in the home setting. So, that that definition is what all of us within the 340B world have been working with for quite some time. Because of that, it is not surprising that there have been HRSA audit findings surrounding the patient definition for years.

Most recently, and probably most notably, was the Genesis Case. So, the Genesis Case refers to Genesis health there in FQHC, in South Carolina, they had a HRSA audit, and the results of which caused them to be terminated from the program. And at the crux of that were findings related to the patient definition. And HRSA said this, this is, this is above and beyond. This is outside of our patient definition. These patients shouldn't have been eligible for 340 Drugs, Genesis said we disagree. Here's our interpretation, here's the way that we are understanding and operating our program. Genesis fought this finding in court, and they were they were successful for the most part. So, a South Carolina District Court ruled that HRSA could not require that 340B drugs only be used to fill prescriptions originating from care with Genesis. So, that was favorable for 340B covered entities for the most part, but the judge did not declare that this meant that 340B could drugs could be used for any prescription for a covered entity patient. So, they fell short of that. Genesis had allowed a two-year look back period when they were thinking about how to define their eligible patient population, eligible patients for 340B.

It's interesting to note that when we look at from a bigger picture, evaluation and management coding guidelines for professional services, CPT coding guidelines state that for purposes of determining whether a patient is a new patient or an established patient of a practice. There's a three-year window. So, if you've been seen within the past three years, you're considered an established patient of the practice. And if you've been seen, you know, if it was beyond that, then you're considered a new patient. So, they were allowing us a shorter window than what is allowed under from a coding and billing perspective, what is understood in the industry from a payer perspective. But they were, they were allowing that two-year look back period, and they were also taking some interpretations, again, on how they were operating their program. So, that ongoing patient relationship, kind of school of thought and the way to look at how you're defining your patient population for purposes of qualifying for 340, B, it has been, and continues to be, an area that is full of lots of opinions and interpretations and has been challenged. But this certainly is an example of

covered entities taking a stand contemplating litigation when they are faced with adverse actions related to their 340B program, and for this, for this situation in particular, the ruling was definitely favorable, although it's important from a covered entity perspective.

If you're hearing this right now and thinking, gosh, should we loosen up our patient definition, definitely think through that. Work with your 340Be legal counsel as needed. Make sure that whatever decisions you make related to the patient definition are included in your policies and procedures are auditable, are something that you all can support from a risk tolerance perspective within the organization, because that Genesis finding the courts and HRSA have been very specific to state that that ruling is only applicable to Genesis at this time and can't be used or applied for other covered entities. In fact, there is a statement to this effect on her says website under their patient definition. I think it's their patient definition education session of their website actually lists this out. So, definitely take all of those pieces into account. And if nothing else. It's a good time to look at the way that you are defining the, you know, your split-billing software parameters, the way that you have your program set up, and see if there are any changes that need to be made there.

So, I talked a little bit about, from a regulatory and legislative update, things that are happening at the state level, at the federal level, talked about the patient definition. Lots of lots of changes, lots of challenges here, and really the heart of a lot of that has to do with drug manufacturer restrictions. So, I want to talk a little bit about drug manufacturer restrictions, and also make sure everyone's familiar with the revamped administrative dispute resolution process, the ADR press process. So, in the middle of 2020, during the COVID 19, public health emergency, drug manufacturers really started to somewhat quietly, enact policies that were aimed at restricting access to 340, D pricing specifically for drugs that are ordered by covered entities that are intended to be dispensed through a contract pharmacy arrangement. So, not necessarily drugs that were going to the hospital for their mixed-use pharmacies, but drugs that were going to perhaps a Walgreens or a CVS or some other contract pharmacy location within the within the 340B program for that covered entity. There was a lot of industry chatter surrounding this. There was a lot of pushback. There were challenges, as you might imagine, because the impact of covered entities on these changes were definitely felt by covered entities, and the impact was pretty significant for a number of providers. And so it's not surprising that that the Office of General Counsel heard some feedback, both from COVID entities and from manufacturers. This caused them to issue an HHS advisory opinion at the end of 2020, in December. And that advisory opinion essentially walked through their fact patterns, their logic, and essentially stated that participation in the program is an agreement the pharmaceutical companies' participation in the program that is is an agreement to sell covered outpatient drugs to covered entities at a price that does not exceed the ceiling price. And so the advisory opinion went on to state that being part of the program does not limit contract pharmacy arrangements that a covered entity can enter into. So, there's no limit on how many contract pharmacy arrangements a covered entity can have, and based on their interpretation, concluded that contract pharmacies are essentially acting as agents of the covered entity under these types of arrangements. So, that was that was definitely favorable for covered entity providers. It kind of reinstated what they felt that they probably already knew, which was, we have a right to do this. We have a right to have contract pharmacy arrangements, and we should be able to get 340B pricing and access to 340 pricing for all of our contract pharmacy arrangements under Bill to ship to just as we have in the past.

Unfortunately, that advisory opinion did not stop the restrictions or even really slow them down. Drug manufacturers are restricting access in several ways. Sometimes they are outright denying 340 pricing for items that are being shipped to a contract pharmacy location. Sometimes they are allowing certain contract pharmacy locations to receive 340B discounted pricing. So, they might say you can have a single contract pharmacy that receives 340B discounts only if you, as a covered entity, don't already also have an in-house retail pharmacy. In addition, there are restrictions that are tied to contract pharmacy dispensation data. So, we're now seeing requirements to report de identified information to 340B, ESP, so that that data sharing that's being required, the impact of covered entities is huge. They are facing declining contract pharmacy, 340B program, savings. They are having to make difficult decisions around what data and how to share that data from an administrative perspective. And then, last but not least, many are expending funds pursuing advocacy in this space and having to work through the 340B ADR process, which we'll talk about in just a moment.

So, 30 plus manufacturers are restricting sales, despite the statute that requires manufacturers to offer 340B drugs to hospitals at the 340B ceiling price despite that. Oh, at the HHS advisory opinion, this is continuing to occur, and when some of these pharmaceutical manufacturers have been challenged. So, far, federal district courts and appeals courts have determined that these restrictions are allowed into the 340B statute, which has been a bit of a blow for providers. I do expect that some of this will continue to be challenged, and it will be interesting to see how it plays out.

So, we can't talk about what's happening with drug manufacturers without also talking about recent activity from Johnson & Johnson. So, Johnson & Johnson had previously published a plan that would require covered entity hospitals to pay the full price for certain brand name drugs and then require them to file a rebate to receive the delta between or that reduced price discount the savings that they normally would have gotten. Initially, they would be getting that money back in the form of a rebate. And so they picked this rebate program for two drugs in in particular, it's interesting that one of which doesn't even have a generic equivalent right now, but those drugs were Xarelto, which is a an anticoagulant, and Stelara, which is a Crohn's disease medication. So, those for those two drugs, their rebate plan was that they were going to roll this out to COVID 19 hospitals. They would not be able to get those, those purchases initially, on 340B pricing. They would have to go through this rebate program. Obviously, it was met with significant industry backlash. Not surprisingly, the American Hospital Association and America's Essential Hospitals contacted HRSA directly that with a number of comments, HRSA had responded in writing, and they warned Johnson & Johnson that this rebate program, this rebate proposal, rather violates John. Johnson & Johnson's obligations under the 340B statute. They threatened to remove Johnson & Johnson from the program if it continued the rebate plan. Interestingly enough, as you can see from this slide, there were, there were a number of pieces of communication, sort of back and forth, back and forth volleying on this up until the very last moment, if you will. So, Johnson & Johnson held their position. Ultimately, HRSA responded with a warning, threatening to remove, remove Johnson & Johnson from the program. If drug manufacturers are removed, they are that penalty is good for a period of a year and comes with a $5,000 fine per infraction. Johnson & Johnson ultimately responded on the day of the deadline that HRSA had given, which was September the 30th, that they would not proceed with their with their rebate plan, but that they held the position that they felt their rebate plan was permitted and would be the best method to ensuring that 340, B drugs only reach the patients in which that they were intended to serve, which is interesting. So, it'll be it'll be telling to see how this, again, continues to play out. Absolutely feel that there are other manufacturers out there that are watching Johnson & Johnson, watching how this is unfolding,

taking notes potentially for some of their own for some of their own actions in the future and planning. I don't think we've seen the end of that. So, while the Johnson & Johnson matter involves disagreement between J & J as the manufacturer and then HRSA, we're going to pivot a little bit, and I want to talk about the administrative dispute resolution process, which is designed to address disputes issues between a covered entity, provider and a drug manufacturer.

So, the process itself is not new, but there are some new rules that have gone into effect earlier this year, earlier this summer, June, June, 18 of this year. So, there are some key differences. The first is the elimination of legal proceeding rules that were previously in place. There is a reduction of panel size and expectations in terms of the claims involved. There are good faith estimate, excuse me, good faith effort, documentation requirements for ADR claims. There is the removal of the $25,000 minimum threshold that previously existed to bring forward claims. And final decisions related to this program are going to be posted on HRSA website so they eventually will be available. And it's important for providers to note that manufacturers can also bring Medicaid managed care duplicate discount claims forward. So, it can, it can kind of go both ways from that standpoint. So, as a covered entity, if this is something that you all are, you are being impacted by, and you're wondering, is this ADR process, something that we should pursue, it's definitely worth taking account to say, okay, what is the frequency of NDCs that are now restricted that we are prescribing? What patient volume does that represent? What drug volume does that represent? What are those savings that we would have had previously, prior to some of these restrictions that we've discussed today? Make sure that any communications that you are having with HRSA or with a manufacturer, make sure that you're saving all of those communications, they may need to be included with the complaint in the future. So, definitely recommend including, you know, saving those documents, either in paper or, you know, in a separate electronic file format. Don't rely just on, you know, a file folder within your outlook, email system or something like that. Make sure it's something that's going to have a good retention period on it, in case you need it in the future. Be sure to assess, as I mentioned, the financial damages.

What are the impacts to the organization from a 340B savings perspective on these restrictions, if you get into a situation where you are not getting 340B pricing, 340B pricing is unavailable, make sure that you're notifying HRSA. Seek assistance. There are plenty of wonderful 340B healthcare attorneys out there that really specialize in this space. So, seek assistance. If this is a sizable issue for your organization, you're preparing to go down this ADR path, it's worth definitely talking with someone to see if they if you need some assistance helping prepare your complaint. And then consider negative impacts of contract, pharmacy location terminations as well in your planning. And then, as I mentioned earlier, consider all state specific laws that are surrounding this topic, covered entities can join together to provide a more cost-effective Avenue if needed for claims. This can also help HRSA by avoiding having multiple claims by multiple covered entities, but perhaps most importantly, if you think that this is something that you desire to pursue. If you are evaluating it, don't delay too long. There is a three-year statute of limitations on claims. So, some we know that, some in the industry, some providers, may say, gosh, we kind of want to wait and see what happens with some of these other organizations that are out there first going through the ADR process. That's fine, just know that that there really is a ticking clock on those claims in terms of what can happen after that period.

So, we've talked a lot about what's happening from a from a state perspective, from a federal perspective, and then from the drug manufacturer standpoint, in terms of restrictions. I want to switch gears a little bit

now and talk about Medicare and Medicare Advantage. So, as quick background, I'm sure everyone is aware, Medicare reduced reimbursement for 340B acquired drugs back in 2018 it was effective in the final rule for 2018 the reimbursement previously for separately payable drugs had been ASP, or the average sales price plus 6% Medicare reduced that reimbursement to ASP less 22 and a half percent for drugs acquired under 340B again, that began in 2018 and that was in place through 2022 during that time period, there was lots of industry pushback. There were there was lots of activity, and there was lots of litigation in this space.

Ultimately, the US Supreme Court found that HHS had violated federal law when it reduced the Medicare payment rates in 2018 So, Medicare reverted back to its prior payment policy of paying ASP plus 22 and a half that happened in September of 2022 and was in effect going forward up until now, from 2023 2020 and into 2024 where we are currently. In addition, CMS did a remedy, if you will, for that reduced reimbursement from 2018 through 2022 by giving lump sum payments to providers that were affected. And so that those lump sum payments occurred during the first quarter of this year, first quarter of 2024 which was great. That was welcome news, certainly for providers in this space, for covered entity providers, but CMS fell short of addressing how to handle Medicare Advantage claims. Oftentimes, Medicare Advantage historically, will follow Medicare guidelines. From a policy standpoint, they do negotiate rates in terms with providers, but from a coverage perspective, have to cover the same things that Medicare covers, and oftentimes are paying based on a derivative of Medicare anyway. So, it's interesting that that there's been no formal announcement, really on how to handle these Medicare Advantage claims. There are providers that are saying, hold on a second. You know, I had I got these, these monies back from CMS. Why am I not also getting funds back from Medicare Advantage plans? And so, there are analyzes taking place now. There are evaluations taking place.

Generally speaking, your provider agreements, your Medicare Advantage contract terms will dictate what how to handle any kind of a dispute on reimbursement, any kind of a dispute on payments or claims, but we really are urging impacted covered entity hospitals to evaluate the impact for their organizations. For some clients in some markets, the Medicare Advantage impacts associated with these reimbursement reductions are even greater than the traditional Medicare impacts. So, definitely something to consider and work through. Contacting your Medicare Advantage plans, seeing if you are able to get any kind of an adjustment there, or if that's something that could be handled in future contracting and future negotiations for future rate setting.

So, clearly, there's a lot of change, and more anticipated change likely coming with the 340B program. There is some uncertainty around what the program may look like in the future, but for the most part, parties agree this program is very much necessary, very beneficial, particularly for the covered entities and the patient populations in which they serve. So, for the time being, we'd really encourage covered entities to focus on making sure that your program is is really a compliant program, is strong. Make sure that you're doing everything that you can, from a blocking and tackling perspective, you're documenting everything that you need to documenting the community benefits that you're able to provide as a result of your 340B savings. It's always a good idea to make sure that you're able to tell your story clearly and concisely as to how the program is benefiting your community.

HRSA audit activity has continued. They are back to in person audits. They have been for a while. Now this slide in particular shows kind of the breakdown of audit activity. This is current as of September the

20th, 2024, because that is the last update date that HRSA has on their site. It will continue to be updated. So, these numbers may continue to shift slightly as audits are completed or as covered entities that have received audits with findings submit their corrective action plans, and those plans are received, reviewed from HRSA and accepted. Generally speaking, I think we can expect to see close to the same amount of audits in terms of volume in fiscal year 2022 there were 199 audits that dropped down to 159 for fiscal year 2023 although we may still have some activity there that's lingering to get to get posted. And then, so far this year, for fiscal year 2024 There are 63 audits that have been posted, overall findings, if we kind of step back and look globally across those three, three years of audits, the findings can be summarized as diversion issues, duplicate discount issues and incorrect OPACE record issues. So, duplicate discount issues generally relate to Medicaid exclusion file errors, either client hasn't covered, entity hasn't included all of their information correctly on the Medicaid exclusion file, or they've put all of their information out there on the Medicaid exclusion file, but perhaps they've missed an MPI. We see sometimes things like that from time to time that haven't been updated. So, that is the finding that has happened time and time again.

Diversion is still a finding, although diversion, as it relates to 340B is a little different from other drug diversion findings from a compliance perspective, typically, that means that a 340B dispensation went to a patient that it should not have, so that can be related to services that were qualifying, that were rendered at an ineligible site, so a location that was not part of the 340B program, or it could relate to patients that were not outpatients at the time of dispensation. So, if a patient had been admitted to observation and then transitioned to an inpatient status and then later received a 340B drug, for example, and we see those findings occurring. It's interesting to note that there are no patient definition findings happening right now as we look, as we look through incorrect OPACE records are a mix, a mixed bag. A lot of times those are administrative issues. They are, you know, clerical errors. Sometimes, if your hospital addresses is 100 hospital drive and you have it incorrectly listed as 100 hospital lane, that that difference, there can be enough to have an incorrect OPACE record finding. So, sometimes it's something as minor as that. Sometimes there are a little bit bigger or more substantial issues. So, you may have an issue with your cost report filing date or the way that your cost reporting period was listed on your OP pace record. Oftentimes we're saying that contract pharmacy information is not current. So, either there's a new contract pharmacy that was added, and that information didn't completely transfer over to the OPACE record for that covered entity or a contract pharmacy relationship is no longer in place, so it's a contract pharmacy that is no longer being used by the covered entity, but they have failed to take it off of their OPACE record, we're also seeing findings related to child sites. So, child sites not being listed or ineligible, off site, outpatient facilities being listed on OPACE. So, kind of works both ways there. So, definitely take some time make sure that you have a clean house, so to speak on all of those link low hanging items.

So, I mentioned already, even with all the all the activity that we've discussed today, some of the litigation, the pushback and the challenges you know, making sure that you've got things listed, set up correctly in your in your program, internally, is the best thing that you can do to continue to support your operations and continue to support the 340 feet program and the need for it in this uncertain environment, when we talk about how to support your program, when we talk about blocking and tackling, some of the things that we're talking about really relate to auditing and monitoring, you should have policies and procedures, you should make sure that those policies and procedures include any updates that might have happened now that we are outside the COVID 19 public health emergency, it's a good time to look back and make sure is everything that's outlined current. Is it correct or the address is correct? Does this reflect what we

are actually doing today? You know, are your provider listings current? I talked about the OPA database issues. You know, those are, those are easy fixes for an organization to avoid having findings later on, down the down the line.

We talked about policies and procedures a little bit, but really making sure, and it sounds very simple, but making sure that as you're doing internal checks, as you're doing internal auditing and monitoring, that any of the things that you are finding within an organization that you're also taking action on, that you're trying to remediate those issues, and you're keeping a good documentation trail and saving those notes, saving those files. In the event of a HRSA audit, HRSA is going to want to see your proof of how you're dealing with your program issues and findings, and that you're maintaining some internal oversight over the program. And sometimes there can be a bit of a gap between the individuals that are responsible for overseeing the 340B program on a day-to-day basis, you know, folks within your compliance team, folks within your pharmacy team, and the individual that's ultimately responsible for signing off and recertifying every year for the program so that authorizing officials.

So, the things on this slide are the things that are listed on the recertification attestation, so these are the things that your Authorizing Official is attesting to for each re-enrollment period. So, they are attesting that everything on the OPA database is correct. It's accurate that your contract pharmacy arrangements are in compliance that they need the essential elements that as a covered entity, that you meet all the eligibility requirements, and that you are going to comply with all of the requirements, that you maintain auditable records, that you have systems in place to ensure ongoing compliance, that you're going to notify OPA if there are any significant changes to your program, and that you understand that you may be liable for any breaches if there's if there are findings later on down the road that result in in a 340B drug being given to a patient that was not eligible.

So, hopefully this content has been helpful as you think about supporting your 340B program, and as you think about maintaining this environment. Going forward, we have more healthcare, regulatory roundup materials coming, so next month, we will be talking about the final rule. It's kind of hard to believe that it's already here. So, we'll have a number of sessions there for you. Thanks so much for being with us today. We appreciate your attendance. Moderator, please close us out.

PYA Moderator **42:45**

Thanks to our presenter Sarah. Later today, you'll receive an email with her contact information and a recording of the webinar. Also, the slides and recordings for every episode of PYA is healthcare regulatory roundup series are available on the Insights page of PYA s website, pyapc.com. While at our website, you may register for their PYA webinars and learn more about the full range of services offered by PYA.

Please remember to stay on the line once the webinar disconnects, to complete a short survey and post any additional questions you may have on behalf of PYA, thank you for joining us and have a great rest of your day.