

Public Workshop on Rule 64D-4

UF/Health Learning Resources Auditorium

Jacksonville
February 17, 2014
9:00 a.m. – 11:30 a.m.

Approximate Attendees: 46

Florida Conference Center

Tallahassee
February 19, 2014
9:00 a.m. – 11:30 a.m.

Approximate Attendees: 32

Florida Hotel and Conference Center

Orlando
February 25, 2014
9:00 a.m. – 11:30 a.m.

Approximate Attendees: 44

Holy Cross Hospital Auditorium

Ft. Lauderdale
February 26, 2014
9:00 a.m. – 11:30 a.m.

Approximate Attendees: 46

FIU Kovens Center

Miami/Dade
February 26, 2014
2:00 p.m. – 4:30 p.m.

Approximate Attendees: 12

Kaiser University

Ft. Myers
March 4, 2014
9:00 a.m. – 11:30 a.m.

Approximate Attendees: 37

Welcome/Purpose/Ground Rules

Suzanne Stevens

This is a public workshop with regard to proposed changes to 64D-4. Sherry Riley, Joe May, Lorraine Wells and Laura Rumph introduced by Suzanne at the various workshops based on which staff attended.

Purpose to review current rule as it exists. You should have gotten a copy of the rule.

Discuss potential changes and the impact of those changes. Workshop is being recorded for the purpose of preparing general minutes and will not be transcribed. The department wants to get your feedback and let us know the potential problems and recommended solutions for those problems.

This is not a hearing, this is a workshop (back and forth dialogue).

Slide Presentation

- Review of dates and locations (as posted in F.A.R.)
- Public open forum to discuss changes and concerns with regard to 64D-4
- Discussion of technical changes proposed to the language in the rule; including items to be added (ADAP and ADAP Premium Plus)

General Themes, Comments and Questions from all six workshops

- Fix the Federal Poverty Level to show 2014 levels
- When defining institutionalized, need a timeline such as greater than 30 days because of hospital or jail. Doesn't give enough time under the circumstances. The intent needs to be clarified.
- Additional workshops were requested in Tampa and the panhandle. Issues of access and not offering workshop at night or those people who work. Some workshops not conveniently located.
- When will a map from ADAP be created and sent out identifying all the changes? There are still people who don't understand all the changes. The community doesn't have tools to identify things have changed. Need something showing all the changes.
- Community involvement and input into policy decisions is key. We recognize the state has challenges but the field has the experience and can bring things to the table.
- Is low income is still defined as gross income which doesn't match the ACA so there will be a discrepancy? Response: Modified Adjust Gross Income (MAGI) will be discussed in place of gross income to align with ACA.
- Transgender services – more training regarding cultural competency for transgender population. They don't want to go to the health department and want more access. People need to feel welcomed and not discriminated against.
- Some people don't use case managers and can navigate the system ourselves. Information not getting to consumers and when enrolled in ADAP there was no information told about being able to use other pharmacies. Issue with DOH is poor communication to consumers and not getting information out. Consistency is the program is lacking.

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- Has a financial impact study been completed as required by the rule process? If not, once this rule is filed it will stop because of law suits. The financial impact isn't zero because all these clients that will be required to go to CVS are currently using pharmacies that are part of the local 340b network. This will take money out of the 340b system and it supports all the drugs for an HIV patient not just the ADAP covered drugs. What will happen, they won't be able to get all medications from CVS and they will have to make several trips and they will stop taking some medications. This is all about dollars from the departments end because the implementation was because of waiting list which is now gone. Why aren't you now using local 340b pharmacy?
 - Since there was so much resistance, why are we now making the PBM the rule since it's not working? Rule will say it must use PBM not specific to CVS once the network is expanded. It also does not say a client can chose the PBM or local 340b. What can we do to make this rule not happen?
 - Are clients and people in the field being solicited for information? Yes, these workshops were shared with everyone and asked to be shared with as many people as possible including providers, consumers, etc. This is the opportunity for input and written comments are accepted until March 7th at 5:00 p.m. Minutes will be sent out as well. Open to all to provide input.

Pharmacy Benefits Manager

- Questions on how savings are calculated from PBM.
- Request to clarify clients currently do NOT have to use PMB which is Caremark/CVS until such time the rule is finalized. Response: clients may choose their own pharmacy but the HIV/AIDS section encourages clients to use the state PBM as it benefits the clients and the program with rebates which help sustain program. The state, however, cannot require a client to use CVS/Caremark.
- How was the contracted pharmacy determined? Through a competitive process. When will it go out for bid again? It is currently in legal and we are waiting for feedback.
- Core of the Ryan White Care Act is choice.
- Encourage a network be modeled after other large states with a PBM and include retail chains so that choice is optimized.
- Specialty pharmacies must be made available which will help increase greater adherence.
- As a Walgreens representative we are concerned about losing long term patients who are being forced to another pharmacy, especially one that is not a specialty pharmacy. Lorraine explained CVS has several specialty pharmacies in the state.
- Choice of pharmacies must be mandated especially since clients have relationships with pharmacies.
- Copay cards should be considered for use that can act as secondary insurance cards. This would solve the issue of case management agencies having to cut checks and would allow pharmacy choice.
- There is nothing in law that requires a PBM. A PBM helps to facilitate data gathering but not required. Any pharmacy can provide the data needed to get rebates from manufacturer. Wanted to go on record to make sure everyone is aware.
- What is the status of the competitive procurement? People understand the original intent, but it's been some years and the current contract is not meeting the needs of the community anymore. We need client choice as well with more pharmacies as a choice. Lorraine agreed and it's under evaluation currently. Waiting to get guidance from legal office. We are into discussions and trying to move that forward.
- Is there a grievance process for people who have mail order through CVS. A local contact or someone at ADAP? There are difficulties trying to get things resolved through 1-800 number.
- Several comments on choice needed for pharmacies and clients enjoying working with AIDS Healthcare Foundation. (AHF)
- Small independent pharmacies need to be included. As a small pharmacy we bubble pack our drugs and this increases adherence.
- AHF takes issues with current PBM methodology...using one pharmacy. Urge the department not to idealize or even consider this structure in any way when developing an ADAP network. There are other sophisticated technologies that can be used to track and maintain encounter data. States like Californian, New York and D.C. do this already. Love motto that DOH uses to "be the healthiest state in the nation" and utilizing one pharmacy chain is not going to lead to that goal. There is something about a specialty pharmacy that is different. They know you as a patient and have a strong rapport

with patients. We need to step up our game. If more money needs to be given by the legislature then we need to lobby around that issue. There needs to be a way to expand the network around any pharmacy that's interested in participating.

- Take issue with suggesting that someone not making the right choice in using CVS is somehow taking medications away from someone else is a very dangerous and flawed policy. Please don't buy into that. Are you aware HRSA is going to convene workshops nationwide around a policy they issued in 2005 around a very complicated issue called full bottle partial claim rebates that many of companies in industry have challenge HRSA as to the statutory authority that allows this. Is the department really counting on a sustained revenue source through rebates? Suggest if you are it is a dangerous road to go down given that's been put before HRSA and the NASTAD.
- Please do not lose sight. Stopping a wait list cannot be the primary goal. 100 percent access must be a priority. Three other states with a wealth of experience in ensuring client choice when it comes to pharmacy. Other models using PBM and can realize savings with broad wide open access.
- Walgreens – help expand program all over Broward County. Worked to increase access to care and stress adherence and retain patients in care and help increase clinical outcomes. Call patients to pick up meds. Most of the pharmacies are part of the HIV centers of excellence. One of two pharmacists that is disease specific. Walgreens staff in HIV best practices and stigma and cultural competency and required to complete a course HIV including virology which is specific to Hepatitis. Locations offer manufacturer co pays cards for privately insured patients and automatically apply them when we can to reduce copays down to practically zero. Saved Ryan White agencies tens of thousands of dollars to help keep more people in care. Have tools to see and HIV free generation but only if we expand access to treatment and not restrict it. Walgreens has a study showing if patients use Walgreens specialty pharmacies they have statistically increase outcomes than those who don't, especially those who also have mental health issues.
- What kind of criteria is being used to pick the PBM to show compassion and empathy for clients and the barriers to access such as hours of operations? Also when talking about choice, ensure consumers' needs are being accounted for in the selection criteria. Needs to be vetted out more.
- CVS had failed to utilize automatic refills which are a very valuable adherence tool. Supposed to have been resolved on last ADAP workgroup call. Concern has never been addressed but Lorraine stated it was resolved in December with no specific date. In the net PBM have a Zero tolerance policies that if clients don't pick up their medication they will be booted from the program (providers). Providers need to embrace meaningful interventions to ensure timely pick up of medication, section needs to fix problem. No doubt there can be improvements. Issue was addressed in October about refills. Lorraine met with vice president of retail and will discuss privately. It's a systems issue not an individual issue. If mandated then the network of providers needs to meet a higher standard.
- Issues with CVS across the state. Other Part B providers are required to attend local consortia meetings. We seem to be remiss to finding someone within this entity to troubleshoot. Do we have a statewide contact for CVS? It's a requirement they attend local consortia meeting and they are the biggest provider so where is that link for us in terms of this process?
- Still waiting on consumer satisfaction survey for consumers, which were asked for several years ago for consumers using the PBM. There has never been a survey to share experiences and challenges. Providers need to meet a standard so a survey needs to get out to the consumers. Survey sent by ADAP staff was offensive and horrified with questions that never touched on quality, etc. Lorraine was not aware of survey sent by ADAP.
- Why was just the PBM considered (it was in the HRSA site visit) and not utilizing the existing covered entities under 340B which would have actually brought in more revenue and opened up the network so patient choice is guaranteed and paid all the copays and deductibles so we could have started with Medicare patients.
- Large pharmacy chains, only one in Clewiston in a 60 mile radius to receive medication. There has to be some consideration for choice and using smaller pharmacies. We keep hearing "we've heard" but we don't get the impression you do hear. There should be some exceptions for those who can't do the larger chains.
- What is the process for exceptions if a client doesn't want to use CVS? If a client wants a choice outside of PBM then an exception process should be outlined in the rule. There are no exceptions and currently clients can choose what pharmacy they want to use.

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- Every PBM has the sophisticated technology to have a relationship with ground level pharmacies. There should be no reason why a local pharmacy that has a digital process can't be used at their function is to maintain the data DOH requires to be able to track utilization. Also, rebates are not a sustainable way to keep program viable. AHF recommends in rule it specify that whatever PBM is chosen they are required to have an open network.

ACA plans and ADAP Wrap Around

- Has the department been able to address the impact of the ACA and the federal exchange with other states in a similar position to see what the impact has been?
- HRSA requires the ACA plans to be cost effective which means the drugs must be covered on the plans and cost less than covering a client on uninsured ADAP.
- Will this rule address the ACA plans as part of this rule?
- If someone enrolled in an ACA plan, can ADAP currently wrap around? No, ADAP cannot help clients in the marketplace at this time. Policy is being sent to the field soon.
- Will someone who enrolled in the marketplace be able to stay in the uninsured part of ADAP? No, if a client has an ACA plan ADAP cannot assist them at this time.
- It's the law to enroll in ACA. Clients will receive a penalty. How is this going to be addressed?
- When can clients transition into ACA plans? A small group of 500 clients has been identified to transition between now and March 31, 2014 in ACA plans. Prioritized based on those on a COBRA plan, those losing PCIP plans, those over \$20,000 in the unassured plan and those with inadequate insurance plans. All other clients will remain in the current ADAP and patient care program until open enrollment at the end of 2014.
- If certain people are being selected to go into an ACA plan, it needs to be addressed in the current rule. We urge you to consider placing criteria in rule.
- Can the state share which plans have been chosen as those the state will wrap around? Hearing just one, BCBS, and it takes away patient choice and AICP has already built up an infrastructure in working with a myriad of insurance companies, why would the state restrict the plans?
- How will clients be notified when they can access the market place and how are clients notified there is insurance viable through the non marketplace that AICP can assist in covering? HCSF has done a terrible job in helping their contracted providers in helping patients navigate to health insurance and brokers to help them navigate and pick a plan. Clients with co-occurring conditions need insurance that are not covered by ADAP. Is outreach going to continue to clients can be better informed about choices?
- Marketplace delay – is their suggested language since we have been told to wait for the past six months to tell the clients they will be facing a penalty even though they will be covered by Ryan White and how they will handle the penalty? There is no good answer right now to this question. Discussion with HRSA about this issue to determine if anything can be done.
- When looking at priority populations you are looking at those who benefit ADAP and AICP Programs. We would like to see priority population include those most in need who are uninsured such as those with co morbidities those at risk of hospitalization. These folks could benefit now and by waiting months could have negative health outcomes. Process left out community input and patient choice.
- Who will do enrollment for the 500 if a client is identified as a Florida Department of Health client and case managers are not allowed to assist clients with enrollment? Response: Local navigators or Certified Application Counselors will not know which plans to pick that are specific to HIV. The Health Council will help facilitate enrollment if needed.
- I'm a navigator and it's kind of easy to choose. Looking at the drug coverage eliminates some then looks at copays and deductibles to eliminate some. Then you are down to a few, mostly silver. I can't figure out why it took the HIV/AIDS section so long when I did it in two weeks. There are 100's of plans all over the counties. Why didn't they get someone in the counties to help?

Symptomatic and AIDS vs. Asymptomatic

- Oppose using symptomatic and AIDS only. MUST be open to all persons HIV positive
- This is not in keeping with current treatment paradigm.
- This concern was stated several times in all six workshops.

CD4 and VL less than six months

- Make the language consistent with the eligibility manual to say six months rather than 180 days
- Consider broadening to annual requirement which would be in line with the federal treatment guidelines and be more cost effective. Some patients are stable and don't need frequent testing.
- There is a difference between stable and unstable clients and the frequency of tests needed.
- Create language that addresses both populations

Eligibility Manual and Application

- Will the eligibility manual and application be referenced in the rule?
- The manual has some items that must be in rule.
- The rule and manual must match especially in regards to AICP and ADAP Premium Plus. Language needs to be clarified.
- Concerned about household – appreciate that some language regarding couples is being deleted especially in state where same sex marriage is not recognized, roommates does not explain specifically that they do not count. Response: Explained this is outlined in the eligibility manual although not specific in rule. Although in manual encourage that actual language be placed in rule.
- Snow birds – provision to suspend eligibility for those going back and forth so clients don't have to go through the eligibility process. Reality in south Florida.
- Can you add language to the rule about "excluding VA" as payer of last resort even though it's in the manual?

Rule Process

- When will the rule be finalized and what is the process? Response: as soon as workshops are done the process to come up with final language will be worked on and once that is complete a notice will be placed in the Florida Administrative Register with the final language. Final rule will be done within the 30-90 day time frame as required at that time by rule promulgation process.
- What is distinction between rule promulgation and rule workshops? Response: workshops start before promulgation and are open to the public for input, comments, etc. Promulgation is once a rule is ready and is posted in the Florida Administrative Register for final adoption.
- When rule goes before JAPC, is there a way for the public to intercede if we are unhappy with the rule? Once posted in the Florida Administrative Register, anyone can request a hearing to comment further on rule.
- If JAPC does approve the rule, does it then go before the legislature for approval? No, JAPC is reviewing and approving on behalf of the legislature.
- Will minutes go to JAPC so they can see that everything is not all warm and fuzzy and there has been a lot of resistance? Not sure of answer.

Funding

- When was the last time the section was allowed to put forth a Legislative Budget Request for ADAP or AICP to the surgeon general to present to the legislature? Response: We have done it for several year and two years ago we received 2.5 million increases in AICP. Something may be going forward this year.
- Surgeon general only talking about obesity and nothing on disease control. Take message back on the fragility of budget, especially with rebates and suggest perhaps it is time to advocate for funds. We are entering a time of great therapeutic success but a very tangled up health care system. Now is the time to ensure the foundation for supporting Ryan White and giving heads up to legislature that HIV/AIDS is still a deadly infectious disease unless taking medications. More important today and try to fight the apathy. Please take message back to show you heard our comments.
- The numbers that go to NASTAD are almost 11 months behind. Do you look at quarterly reports? They should get posted to Bureau website. Because we get asked questions from an advocacy standpoint, we need to point out the state contribution. Is budget available publicly with breakdown of GR and Ryan White?

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- Rephrase to what do we need and what would it cost? How do we prioritize all other part B services? Community may say all bells and whistles are nice but we need medicine. Want to expand to open to all HIV positive. HRSA expects us to serve population and reprioritize as needed. Within the law the Section must have drug completion where Part A's have far more flexibility. You have money on the regular part B side that could very easily be moved to ADAP if needed to. We need partners at the table so people can hear and understand and when decisions are made they understand. It's not about getting more money but moving dollars to make it work.
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Recommendations

- 1) It is Vital to add Marketplace plans to the list of eligible coverage types for both AICP and ADAP to provide wrap around services such as Co Pays, Premiums & Deductibles immediately, as there are already some clients that have made the transition as requested out of the Ryan White program and are now experiencing a variety of costs to access their care.
- 2) Expand the AICP & ADAP categories to include asymptomatic clients. Current science & Federal guidelines strongly urge accessing Medication therapy (and therefore wraparound subsidies for associated costs) and getting to an undetectable HIV level as standard of care in the current medical environment. Therefore, the vague & often misinterpreted symptomatic phrasing should be deleted from all references in the Part B Program.
- 3) Build into the upcoming Procurement process a REQUIREMENT for the next successful vendor for the statewide PBM to have a Pharmacy Network with multiple HIV Specialty pharmacy providers available statewide for client choice. This will also provide adherence mechanisms, an additional mechanism to ensure clients stay in care, as well as other value added services.
- 4) Utilize the State's existing advisory system; both the PCPG and the ASTAC have decades of experience at the local level providing direct services to actual clients. They can assist in determining which Marketplace plans are best in each region, as well as a host of other operational issues that may yet not be accounted for by State level staff.
- 5) Review consistent interpretation of policies within the various ADAP eligibility staff around the state. Use examples when issues are not addressed appropriately so all staff can learn from mistakes. Track all staff to ensure some are not missing several calls in a year etc....
- 6) Reinforce & Codify the Part B service provider requirements for future Vendors of ADAP services statewide as well as locally. Each region needs a local contact person to interface with directly, as many issues could be solved locally and quickly if we had the connection in place. We ask that you request this of your existing vendor, understanding this is not a contractual requirement for them at this point, but hopefully they will oblige this statewide request.
- 7) A request to revise the eligibility to the new "MAGI" to be consistent with other payor sources.
- 8) We need as soon as possible from the ADAP Program a 1 page overview of all existing functions & services available. Understanding that this will change over time and frequently. There is too much confusion in the field, and there needs to be more clarity in terms of what is offered and what is available for clients at the local level.
- 9) Expectation that some form of response will be provide at the upcoming PCPG meeting in Tampa. A full report of what transpired and what the state identified as trends & themes from with various meetings across the state.
- 10) A meaningful discussion of timelines & available services for the future as ADAP adapts to increase wraparound coverage for plans, expanding & revising guidelines, and what we can expect for the upcoming year from the Florida Dept. of Health.
- 11) Dire need to rectify a major statewide problem: CVS is not allowing auto refills for ADAP Premium plus clients. We have received written complaints from various ADAP Clients from across the state experiencing this problem, greatly contributing to people running out of their medications while trying to fix this problem. It is still happening as of this week.