Managing Lymphoma

Chronic Lymphocytic Leukemia in Rural America

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Farrukh Awan: Hello, I'm Farrukh Awan. I'm an Associate Professor of Internal Medicine and Director of the Lymphoid Malignancies Program at the Harold C. Simmons Cancer Center at the University of Texas Southwestern Medical Center in Dallas, Texas. Welcome to today's program. *CLL in Rural America: A Cancer Care Performance and Quality Improvement Initiative for Clinicians in Rural Practice*. During this program, we will discuss the issues surrounding the treatment of CLL in rural America. Alan Morgan, who is the Chief Executive Officer of the National Rural Health Association, will begin our program with an overview of the national and local challenges in rural cancer care and the obstacle faced by rural clinicians when treating patients with CLL. I will then provide an overview of the current treatment paradigm of CLL and best practices in the management of these patients, and then we will conclude with an overview of the CMS and the MIPS performance and quality improvement in rural practice including the worksheet and resources for rural cancer care. So with that, we will now begin our program with Alan Morgan's discussion of the challenges in CLL in rural cancer care.

Alan Morgan: Thank you, Farrukh. I'm Alan Morgan, and today I want to provide you with an overview of rural cancer care, both nationally and locally in the United States. Now, it's important to note that when you talk about Rural America, it is not just simply a small version of urban. It really is a unique healthcare delivery environment. It's an area where we're facing workforce shortages nationally, in a space where you have vulnerable populations and, at the same time, you're facing chronic poverty across the small towns all across the United States. In rural America, only 9% of the physicians practice, and at the same time, it's important to note that 77% of the 2050 rural counties in the United States are primary care health profession shortage areas. More than 50% of rural patients have to drive more than 60 miles to receive specialty care. So right off the front end, you can easily see that you can't apply urban solutions in a rural setting, certainly when talking about cancer care.

Now, on a positive note to the current pandemic that we're facing, telehealth regulations both at the federal level and the state level have seen tremendous relaxation over the last six months to allow for further expansion of telehealth services for specialty care, which is so vitally important because specialty care in a rural context really rarely exists. However, it's important to note that while the nation's rural hospitals, on the whole, have access to broadband, high-speed broadband, many of the surrounding rural health clinics or rural community health centers still

do not have adequate broadband to do a lot of the specialty consultation and services that you might expect in a rural context.

So let's talk a little bit about what we were seeing prior to COVID to give a sense of what we're looking at from a rural provider standpoint. In February of this year, there were roughly 2000 rural hospitals, now 1300 of these have fewer than 25 inpatient beds, 700 are larger facilities, what we call prospective payment system facilities. At that time, before the pandemic arrived, roughly half of these rural hospitals were operating at a loss and only had 30 days' cash at hand, and more than 400 were at risk for closure at that time. When we had the pandemic hit for these rural facilities, they closed many of their outpatient and elective procedures, many of their screening activities, further exacerbating their very precarious financial positions putting them all at risk. And that brings us to a very, very important point before I go any further, and that is, while I mentioned that half of the rural hospitals were struggling to keep open, that does indicate that half were actually succeeding. And we need to make sure at the front end that we recognize these rural facilities are built for primary care and general surgery, not really designed for pandemic response. And when it comes to the quality of care, CMS metrics, the Centers for Medicare and Medicaid Services, indicates that basic services, primary care, screening activities actually operated the highest level across the United States. So the real issue going ahead is in this situation where rural hospitals are threatened and you have workforce shortages, how do we adequately address rural cancer needs among a population that is older, sicker, and poorer? In Rural America, the median age of adults living is 51 years. Now, for CLL, the average age of diagnosis is between 60 and 70, so you can already see a linkage among that. Rural areas have higher rates of several health risk factors including obesity, diabetes, and smoking, which all lends itself to the decreased life expectancy in some rural communities of up to 20 years less life expectancy than the urban counterparts. And that's important to look across all potential ages on that.

Which brings us to the issue of rural cancer care in specific and the mortality rates. Rates of cancer are higher among rural Americans and that is also the case with CLL. Minorities, especially Native Americans, consistently die prematurely in a rural context as well, too. Now, not all cancers are the same. I mentioned, there is a higher prevalence of CLL among rural populations. But it's important to note across the breadth of rural cancer, the diagnosis of cancers in rural populations is lower than that in urban across the board; however, mortality is greater. Now, the reason that this is important is it highlights barriers to care, both workforce, transportation, and structural obstacles to receiving care in a rural context. And it's important to note and recognize that while dealing with these patients as well. In many cases, unlike urban, you're going to have a much higher prevalence of financial hardships, the ability to be facing uninsured or under insurance, shortage of physicians, and distance to treatment facilities all combined to make cancer care exceedingly problematic in many of these rural communities. Not to mention in several small towns and healthcare systems in a rural setting, they are not simply set up for this type of monitoring, which is part of the reason why we're having these sessions here today. And, of course, an overarching issue among this is the role of social determinants of health. Their socioeconomic factors, cultural differences that all influence trust among rural populations with rural providers. It's important to keep that in context while delivering care to these patients.

Now, if you look at a map of the rural counties in the United States, you'd see that there is a strong correlation among the following slides as I go through them fairly quickly. Rural America

is poor and, in fact, you can see the rural counties pronounced just by a map looking at poverty across the United States. Overlaying that with the prevalence of chronic health conditions that we're seeing, you see again the same rural counties lighting up. And obesity is a good proxy for many of these rural chronic health conditions, again, you see the same rural counties that are older, sicker, poorer, all coming together in these small towns across the United States. So, again, for the purpose of CLL, the active monitoring of this disease as it goes forward is a paramount concern. Looking forward and part of the importance of this particular program is throughout the history rural providers have actually led the efforts to redesign the healthcare system as we know it, one from being based on volume to being based on outcomes. And because of the small settings that we see in clinics and small rural hospitals across the country, there is the ability to innovate, try new things. And when practices and procedures do not work out, to change and modify the work more effectively. As we move forward, we're going to see more of this new innovative payment models moving forward. This is not a passing fad, but a new way of delivering healthcare and particularly specialty care across the United States. Moving forward, we're going to see the shift among rural communities into what's known as global payment models, which again ensure an adequate supply of revenue coming in the doors, but ensure that the providers are actually keeping the patients healthy, well-monitored, empowering them to take care of their own healthcare status, and transforming healthcare as we know it today.

With that, I want to thank you for your attention to this brief overview of rural health and rural cancer care across the United States. With that, I will now turn it back over to you, Farrukh. Thank you.

Farrukh Awan: Thank you, Alan, for a great discussion. I will now review with you the current treatment algorithm for CLL and best practices for managing patients with CLL in the clinic, so this is the topic of my discussion. So we'll basically talk about a very brief introduction of how things have changed for CLL in the last decade or so. We will then talk about advances in frontline management and then treatment of patients in the relapsed setting. So we'll start with the definitions and the prognostic testing and why that is important and what is considered standard of care at this point. CLL is the most prevalent leukemia in the Western Hemisphere. Fortunately, our patients live a long time, and we do get around 20,000 new patients a year in this country, and we have close to 200,000 survivors, if not more. The median age of diagnosis is 71 years and it's mostly men, 2:1 ratio as compared to females, and the vast majority of our patients are asymptomatic, and they are diagnosed on a regular blood count that the PCP might have performed. So the vast majority of our patients are asymptomatic when they first present of their CLL.

So how do we define CLL right now? And this has been updated since at least 2008 when the iwCLL criteria was first published and then this has been updated in the 2018 criteria. So to define or to diagnose somebody with CLL, you need to have at least 5000 cancer cells in the circulation, and by definition, that means that you have to do a flow cytometry, which documents the presence of 5000 CLL cells, and those cells need to have a CD5 and CD23 coexpression on their surface and that, by definition, is considered CLL. A lot of times, we see patients who might have a smaller clone of CLL-like cells. They have 5 and 23 expression, but the absolute count on flow cytometry is less than 5000. And in that setting, if the patient does not have any organomegaly, no hepatosplenomegaly, no lymphadenopathy that you can palpate, by definition, those patients are considered monoclonal B-cell lymphocytosis, so almost analogous

to what we have for MGUS for multiple myeloma. So a lot of our patients, unfortunately, are MBL patients or monoclonal B-cell lymphocytosis patients, but they are labeled as CLL because the flow cytometry says that they have a CLL-like population. MBL is another beast in itself. There are different types of MBL. They have different prognosis. There's a high-count MBL. There's a low-count MBL. There is CLL-type MBL. There is a Mantle-cell type MBL. So we have to be cautious that to label somebody as CLL, we have to ensure that they have at least 5000 cancer cells, which is the CLL phenotype, the CD5 and CD23 positive cells. The other important thing in this situation is that the lymphocyte by itself, the 5000 absolute lymphocyte count that we get on a differential count on a CBC, is not enough to diagnose somebody with CLL anymore, so you have to have a flow cytometry done.

One of the biggest challenges we face is, the patient gets diagnosed, they're very anxious. They come to us and they say, "Doc, you know, I have this cancer. What do we do?" And then you tell them, "Hey, I'm not going to do anything. I'm just going to watch you." And that is the hardest discussion to have with a patient. And the way I help my patients out is that early treatment has never shown to prolong survival in CLL. And actually, for older patients above 70, historically, when we have treated those patients early, they have a shortened survival because they have treatment-related problems. So because of that reason, we will initiate therapy based on a certain criteria that we have to meet. And that's a discussion that you need to have with your patients, which is what I have with my patients. That that criteria, this is what it's called, the iwCLL 2019 criteria. That basically has two big components: One component is the subjective component, which is essentially a patient-driven component, and the other component is more of an objective component in which we follow the numbers. So, what are those? Basically we look at the B symptoms, we look at weight loss of more than 10%, we look at significant fatigue related to the CLL after excluding other causes of fatigue, we look at intermittent fevers of more than 100.5 for more than two weeks without evidence of infection, we look at night sweats. So those are the subjective criteria that we use to consider treatment in some of our patients. At the same time, we are also following the anemia of less than 11 or thrombocytopenia of less than 100. We have to document that they have significant splenomegaly of more than 6 cm below the ribs, and we have to have either symptomatic lymph nodes or significantly enlarged lymph nodes around 10 cm or so, which is roughly 5 to 6 inches. So fairly substantial lymphadenopathy is required before we consider somebody as eligible for treatment. Small lymph nodes are very common in patients with CLL. They fluctuate over time. They will fluctuate with regards to infection issues or other insults, so we don't necessarily treat patients based on just the presence or absence of small lymph nodes. A question that gets asked all the time is, what about the white count? The white count is never really used as a cutoff or as a reason to treat anyone by itself. The white count is used in conjunction with all these other signs and symptoms, so I don't ever use the white count. Some people use a lymphocyte doubling time of less than six months, and that is a soft reason to treat somebody. And if you want to go by the book, a lymphocyte doubling time means that the absolute lymphocyte count has to be higher than 30,000, so if it goes from 15 to 20 or 15 to 30 in less than six months, that doesn't count. But if it goes from 40,000 absolute lymphocyte counts to 80,000 absolute lymphocyte counts in less than three months, that could be used as an indication for therapy in some patients. Have I ever used that? Very rarely do I use it. A lot of times, patients have other symptoms along with that and they have rapidly progressive disease, and that makes perfect sense in those patients to consider treatment. So these are the reasons when we initiate therapy, and that's exactly why we need to have a really in-depth conversation with our patients and make them very comfortable about using these things.

What is the B-cell receptor targeting? We know that the CLL cells are turned on perpetually, so they don't die. They survive a long, long time. And why does that happen? That happens because of the presence of this activation of the B-cell receptor, which basically gets turned on all the time, and as a result, there are downstream signals in the cell which provides a survival signal. Right now, we can actually target any of these intermediates: The Syk, the BTK, the PI3-kinases, which provide that survival signal. The shift has been away from chemotherapy and targeting these particular molecules, which we really understand very nicely nowadays. So most of the discussion is going to be about these new agents which some of them are approved, some of them are in the process of development, and they've really revolutionized the way we treat CLL at this time.

What about the prognostic markers? What do we do? The most important one is the FISH testing. Another issue that we run into all the time is when patients come to us, invariably the primary care doctor or some other physician has told them that this is a good cancer to have, and unfortunately, that's an inaccurate statement. There is no such thing as a good cancer, and CLL is not one disease. CLL is a very heterogeneous disease. There are some people, especially if they have a 17p deletion, who do really poorly. On the other hand, if they have a 13q deletion, sure, those patients may not need treatment for a long time and they have an excellent prognosis, but the point is without doing a proper FISH test, specifically for CLL patients, because it's a specialized FISH test, without doing that, you cannot document or you cannot comment on the prognosis. Because what if the patient has a 17p deletion and needs treatment within nine months? That is exactly why we need to know what kind of a cancer, what kind of CLL are we dealing with, what type of CLL are we dealing with? So it's extremely important to get the FISH testing at the time of treatment, either initial or relapsed. What other markers do we do? We've moved on from the Rai staging, we can still use that, but we can do much better than that. And this is one of the markers that we have or one of the tools that we have, this is called the CLL-IPI score. And basically it has age and the Rai stage along with beta-2 microglobulin, and the most important thing is the IGHV mutation analysis, which is different from the IGH clonality assessment that we do for B-cell lymphomas. IGHV specifically looks at the variable region of the heavy chain, and it’s a specialized send-out test. Very few people in this country get it, and as you can see from the score, it has a substantial impact on the overall prognosis. But the most important thing that we absolutely have to do is to do number one, the FISH testing to make sure that the patient does not have a 17p deletion, and along with that, we have to request a TP53 mutation analysis, which is a genetic sequencing test that looks at specific mutations in the TP53 gene. And without sending that test out specifically, the FISH testing will not answer that question because the FISH testing only looks at certain deletions or additions or mutations, but it would not give you the whole landscape of the TP53 gene. So it's important to do both the TP53 mutation analysis and the FISH testing along with the IGHV, because those three combined will give us 6 out of the 10 points in this score. And if you have a TP53 mutation, you will automatically get into the high-risk group, and those patients tend to have a poor prognosis. So it's important to do these tests at the time of initial treatment and also subsequent treatment.

Let's move on to, how are we treating CLL nowadays in this country? What is considered standard of care? Chemoimmunotherapy has been the backbone for treating CLL for the longest time. We’ve used FCR in the past. We've used bendamustine and rituximab, so they're tried and tested. We have long-term data with those. It's a fixed duration, six months and you're

done. Four to six months depending on tolerability, and it might be the cheapest option. On the other hand, chemoimmunotherapy also has a lot of side effects. Specifically with regards to FCR chemotherapy, up to 9% to 10% of those patients can have a secondary hematologic malignancy or MDS or AML, which is very, very high risk, and also almost 30% of the patients can have other secondary neoplasms. So treating somebody with FCR right now is probably not a good idea. It's definitely not suitable for all patients, especially the older patients, and since most of our patients are above 65, most of them would not be eligible for FCR anyway. It can also cause damage to the marrow, and then it's very immunosuppressive, so we get a lot of infectious issues. So there are a lot of problems with chemoimmunotherapy. And can we do better than that? And that has historically been the question that we need to answer. It turns out that one of the major advances that happened was with ibrutinib. The ibrutinib was compared to chlorambucil, and if you look at the forest plot on the right side, you can see that across the board, ibrutinib was clearly better than chlorambucil. And as a result, ibrutinib got approved both for the upfront setting and for the relapsed setting for 17p deleted disease for all-comers with CLL. Ibrutinib was approved based on multiple studies of which RESONATE was the first one. And then the big question that needed to be answered was, "Is ibrutinib better than bendamustine-rituximab, especially in the older patients?" And this is the ALLIANCE trial, which was recently reported. These patients were randomized to ibrutinib-rituximab, ibrutinib, or bendamustine-rituximab. At that time, when the study was being designed, there was some thought that the ibrutinib-rituximab combination might be better than ibrutinib alone. It turns out that there was no difference in the ibrutinib-rituximab arm or ibrutinib alone, but it was clear within three years of follow-ups, a very short follow-up still, that bendamustine-rituximab is inferior to ibrutinib in terms of progression-free survival, and it also appears to be the case in terms of overall survival, and there was no difference in terms of progression-free survival between the I/R arm and ibrutinib arm. So, at this point, there is no rationale or reason to add rituximab to ibrutinib. What about different types of patients, patients who have unmutated IGHV, patients who have high-risk disease, patients who have low-risk disease? Across the board, patients who got chemoimmunotherapy did worse with the treatment as compared to patients who were on the ibrutinib arm. This is, again, data from the younger patient cohort on the ECOG study. Similar design, ibrutinib-rituximab was compared to FCR for patients who were younger, 70 or younger, and in those groups of patients, ibrutinib-containing arm was better than FCR and not just progression-free survival, but overall survival was also significantly better in that group within a short follow-up of three years. There has been this argument that you've never shown an overall survival advantage with these drugs so there's no justification using that. But both with the ALLIANCE trial, we don't have overall survival data mature yet, but there is a clear-cut progression-free survival difference in the older patients as compared to B/R, but in the ECOG study, which was a sister trial with FCR, it clearly showed a survival advantage in all-comers when ibrutinib-rituximab was compared to the FCR therapy. So there really isn't a reason to use FCR in the younger patients anymore or bendamustine-rituximab in the older patients anymore. I think it has been clearly shown now that ibrutinib is of superior drug. Now, there's some debate still that patients who have a mutated IGHV, those patients might do really well with FCR, and that's a group of patients that is being debated right now, so we don't have that follow up right now with the ECOG studies, and hopefully once we have that, we will have more information. What about other options? Because one of the arguments against using ibrutinib is the indefinite time period that ibrutinib has to be continued. And for those patients who may not be candidates or may not want to be on perpetual therapy, venetoclax in combination with obinutuzumab is approved. It's a 12-month regimen, and it has been shown to be better than chlorambucil-obinutuzumab and it is now being used in some patients who want

a time-defined option. Very, very promising results to your progression-free survival of around 88%. But still, relatively early follow-up, so we'll have to wait and see how these patients do in the long term.

Another really good option, very exciting option, alternative to ibrutinib is acalabrutinib. This was recently presented and published. This is basically acalabrutinib in combination with obinutuzumab versus acalabrutinib alone versus obinutuzumab and chlorambucil. So essentially, patients who would not be considered ordinarily for chemoimmunotherapy, and in that patient cohort, acalabrutinib-containing regimens were significantly better than chlorambucil and obinutuzumab. Now, one interesting fact seen in this particular trial is that the patients who got acalabrutinib in combination with obinutuzumab tended to do much better, although the study was not designed to look at that difference. So it's exciting whether obinutuzumab addition to acalabrutinib will become standard of care, we don't know. But at this point, it appears that acalabrutinib by itself is very promising, and if you add obinutuzumab you could potentially improve the progression-free survival, but not by much. But regardless, acalabrutinib appears to be better than the alternative chemoimmunotherapy-based regimens that we have.

At this point, to summarize all the data, so if the patient does need to be treated, obviously, if you don't have an indication to treat, you observe those patients. But if you do have an indication for treatment, you start off by looking at the 17p status. If you have a 17p status, you start with either ibrutinib or acalabrutinib, and venetoclax with obinutuzumab is also a reasonable option, especially if the patient does not want indefinite therapy. This does not change with age or comorbidities. Some people argue that bendamustine-rituximab is an option, but as I've shown you before, ibrutinib-containing regimens are clearly better than bendamustine and rituximab, but since bendamustine and rituximab is fairly commonly used still, I have it on that list, but it is with a lot of reluctance that I would ever consider that because most of the patients will do just fine with ibrutinib or acalabrutinib, and if you want to stop, you can also use venetoclax. The only argument right now that is available or that is still there in the field is what about the really young fit 40-year-old patient who has mutated or good-risk CLL without 17p deletion. So in that specific very good-risk young, healthy person, you can make an argument that FCR might still be an option, six months, and you can have a prolonged remission in excess of 10 to 15 years, and that's still an argument that is being made for justifying the use of FCR. However, as I've told you before, toxicities with FCR, the secondary myeloid neoplasms, the secondary malignancies risk is significantly higher with FCR. So I'm generally not a fan of using FCR in any setting, and if the patient does want a time-limited option, I would offer them a venetoclax-obinutuzumab-based treatment option.

So this is just my summary of how I would treat the frontline patients, very similar to how I would treat patients in the relapsed setting. But just to refresh our memory, this is the ibrutinib RESONATE trial, which was comparing ibrutinib to ofatumumab, which was another alternative approved agent at that time, and ibrutinib was clearly better, and as a result, it got approved in the relapsed setting. And then similarly at the same time, venetoclax-rituximab was compared to bendamustine-rituximab in the MURANO trial, and it was clearly shown to be better than bendamustine-rituximab. So there is really, at least in the progression-free survival, advantage was clear for the venetoclax-rituximab arm. Also more recently, we got data from the acalabrutinib study, which basically randomized patients to acalabrutinib as compared to idelalisib-rituximab or bendamustine-rituximab or basically dealer's choice, and it was clearly shown that acalabrutinib was better than IDELA-rituxan or bendamustine-rituximab. In this

particular study, most of the patients were treated with IDELA-rituximab and it's been now clearly shown that acalabrutinib is superior to that combination and also superior to the bendamustine-rituximab combination. So, really no reason to use B/R in the relapsed setting if you have a patient who has not had BTK inhibitors before.

Just to summarize, we have, again, similar to what we would do in the frontline setting, if the patient does not have reason to treat, we observe them. But if they have an indication to treat, we go by what they've had in the past. So if they've had chemoimmunotherapy in the past, then it's wide open. You can use ibrutinib, you can use acalabrutinib, and if they want to get a time-limited option, they can use venetoclax-rituximab, which is a 24-month time-limited treatment for venetoclax. Now, if they've had a prior BTK inhibitor like ibrutinib or acalabrutinib, in those patients, I would start off with venetoclax and rituximab. That would be my first choice because the PI3-kinase inhibitors do not seem to be as effective as venetoclax-rituximab in patients who failed a prior BTK inhibitor. Similarly, if somebody was treated with venetoclax up front and they stopped because of the time-limited option, they can either repeat the BCL-2 inhibitor or venetoclax, or if they truly progressed on venetoclax, those patients can actually be treated with a BTK inhibitor, and that had shown promising early responses and it appears that BTK inhibitors would be reasonably effective in patients who failed a BCL-2 inhibitor like venetoclax. So this would be my summary. This would be how I would approach a patient who has relapsed disease in the modern era. I pretty much moved away completely from chemoimmunotherapy unless it's a very unique patient in which none of these options would be reasonable choices. So prognostic assessment is extremely critical. Without knowing the TP53 mutation status, the FISH status, the IGHV status, we cannot really make an informed decision. We cannot talk about prognosis. Do we follow the patients every three months? Do we follow the patients every six months? All of those decisions can be made much easier if you have access to the prognostic testing. Similarly, chemoimmunotherapy or chemotherapy alone has very limited role in patients with CLL. And as I've said before, it's a very unique situation in which patients would be eligible for chemoimmunotherapy and not BTK or BCL-2 inhibitors. Sequencing - How would you sequence one after the other? Those are questions that are being addressed right now. So it's critical for patients to go on a clinical trial at every possible opportunity, and it's very important to involve the patient in this decision making. Every patient has a different perspective on how they would like the treatment to go. Every patient might have different comorbid conditions, kidney issues, hypertension, atrial fibrillation. These new agents, while they're exciting, they also have unique side effects, and as a result, we have to be aware of those and have a discussion with our patients. Now we'll wrap it up, and we will conclude with an overview of the CMS MIPS performance and quality improvement in rural practice.

Opal Greenway: Thank you, Farrukh. I'm Opal Greenway, a Director at Stroudwater Associates, a consulting firm that provides services to providers nationally, and really focused on providing services to rural healthcare providers across the country. So today we're going to be talking about the CMS program for MIPS performance and quality improvement in rural practices, specifically for the CLL and a rural cancer care initiative. Since you have these slides that are here at the beginning, today we're going to be talking about the rural cancer care resource guide and the program from CMS for small and underserved rural practices. We'll go through that really quickly since you'll have the slides, and the slides have the resources available for you, and spend today really focusing on the MIPS performance and quality improvement — what does that consists of, what do you need to take in mind, and going over that worksheet that you have available to you, and what you need to do with it. So these first

few slides cover what is provided from the rural cancer care resource guide. You have access to a lot of education and resource materials, as well as the resource libraries and worksheets that will help you actually build out what you need to do for the MIPS program. Specifically for small and underserved rural practices, CMS has provided a program for five years to specifically help these rural providers set up their programs. There are specific requirements to be able to have access to these. It is a free service that is provided for small practices with 15 or fewer clinicians. In my experience, that does make up the vast majority of the rural providers here in the United States. To be able to qualify, you need to be in a rural area, a health professional shortage area, or medically underserved area. So, again, most of the practices, you can look up online whether or not you actually fall into that, but the vast majority of the clients that we work with do fall under that category.

There is specific program level support when you meet those different requirements, and they will help you actually go through and figure out the different QPP/TPP parts of it, of what you should report, whether or not you should be included in the program, should you apply for specific exemptions, what are those exemptions that might apply to you, how do you submit your data, what are the different forms you need to fill out, and how do you actually transition into the APM model or an advanced APM, which is the whole focus of MIPS, as we're trying to move along that spectrum towards a value-based payments, where we move from MIPS over into an APM. We've provided on this program level support slide information specifically for South Dakota so that you can find that information. Each state has their own specific office to provide resources to you. Even when you have actually access to practice level support, and one of the important things that you should start with is doing a readiness assessment to understand where are you, before you think and choose your metrics, go ahead and do an overall gap analysis of understanding where your practice is and how prepared you are for participating in the MIPS program. Having access to this kind of support, to actually do this gap analysis for you and help your practice guide you through it, will make the process significantly easier.

Now, we're going to talk about the overall MIPS program and what you, as a practice, need to be keeping in mind, what is it comprised of, and what should you be reporting. So keep in mind that the goal is to move towards value-based payments. The MIPS program under MACRA was designed specifically to move practices further across the spectrum from a fee-for-service model over now into a population health value-based payment world, right. This started off with PQRS and meaningful use and other programs like this. MACRA was designed specifically to accelerate this process. So under MIPS, CMS is now going to evaluate practices performance in four general categories—quality, cost, improvement activities, and promoting interoperability. A lot of these may be very familiar when you get into the details of them, such as the quality is actually a replacement for PQRS. Promoting interoperability is the replacement for meaningful use. Each one of them has a little bit of differences from what they were historically, but they should be somewhat familiar to you. Notice those weighting of these scores, those are going to shift. They already have shifted, such as cost should only be 10% rather than 15%. And knowing that, we pay attention to, all right, they're trying to give a lot of weighting towards the areas that we're already familiar with, such as quality and EHR, and those are going to be shifting to focus more on improvement activities and cost. The cost information, we're not going to spend a lot of time on today because you're not going to be reporting cost. Medicare is basing your cost score on actual claims data, and a lot of physicians I work with in individual practices, that’s still the area where they have the least amount of influence. In a rural setting,

most of you have already cut costs as much as you possibly can. So how can we focus on the other categories to generate our actual MIPS score? Whatever your final MIPS score is, that is going to determine whether or not you receive a negative, neutral, or positive MIPS payment adjustment. That adjustment is going to apply to your physician fee scheduled payments that you receive the following year, and it is a percentage adjustment. So if you do really well, you might get 2% added to your MIPS payment for the following year. And then usually it's actually because for what you do in 2019, you report that data, it actually applies two years later to that payment.

So let's talk about specifically for rural practices. There are flexibilities that are afforded to the small and underserved rural practices. One of the important things has been the exclusions. So a lot of this MIPS and MACRA has been announced back in 2015, it started really getting implemented in 2017. There hasn't been a lot of focus in the rural markets on MIPS and MACRA because of so many of the exclusions that existed. These exclusions do still exist. However, the bar has been raised in meeting those exclusions each year. So previously, if you had less than 100,000, now it's 90,000 for being able to qualify for this. Some practices are more likely to fall under one of these exclusions. The pedia practices that focus very much on pediatrics or ob/gyn practices tend to end up falling under an exclusion due to their very small Medicare payments that they receive. It doesn't make sense for them to spend a lot of time in this. There will be future programs that will address those types of programs. And we'll note that Medicaid is also moving in this direction. And with a program, that we're not going to talk about today, CPC Plus, a lot of other commercial payers are also moving in this direction. So I encourage, even if you qualify for an exclusion from the MIPS program, pay attention to what's going on with it and assess your practice and move your practice in that direction because it is coming for you, even if you're not there yet. There's also exemptions for and that will allow it to be easier for you to participate in MIPS, whether it's through a virtual group, if you're a solo practitioners, you can group together with other physicians and clinicians to report, if you have 10 or fewer clinicians already in your group, you have an option to do virtually. I highly recommend reporting with a group if you are well aligned. Don't just pick random practices out there. But if there's already practices that you're dependent on, that you do referrals with, that you might be considering being part of an ACL with, those are the different groups that, if you are well aligned, it is much easier to report as a group virtually or otherwise than it is to do it individually. So the additional flexibilities are we do allow that as clinicians. You do have the option of reporting both as individually and as a group level, and how those are tried out. I personally, as I said, most of my practices have been more successful doing it at the group level rather than doing it individually. But an important thing that we'll talk about more with the quality initiative is that the individual level, trying to pay attention to your individual performance and not overly relying on the group to be able to do the performance that will get you those payment adjustments.

Let's talk about the reporting requirements for the quality performance category. This is the one most of you should be all familiar with because of PQRS. So under the quality performance category, you have an option to report under three different categories. You can take six quality measures, at least one of which has to be measured high weight for a high priority measure or an outcome measure. There's a lot of focus on patient reported outcomes, so pay attention to how have you been doing in your pay, had you already tracked patient reported outcomes. That's really focusing that you can give a lot of weight to if you select that as one of your measures, and they are moving in the direction of reinforcing that. That if the patient reported

outcome, and not just what you're getting back from, like, lab works and what you're seeing in your data. And the reason for that is because they want you, as a clinician and as a practice, to provide more education to your patients to make sure they're very well informed about their treatment plan, and what initiatives they need to be making lifestyle wise or otherwise, and have that education be ongoing so that you can have improved patient reported outcomes. You may also do a defined specialty measure set or some specialty measure set. If you have fewer than six measures, you have to submit the information for all of the ones that are in your subspecialties. And the third option is to do all quality measures included on the CMS Web Interface. So there should be a link for that and you can be able to go on to CMS and look at all those different measures that are in there. One thing I would recommend, instead of focusing on what do I have to report from a quality picture, think about your population, and as a physician or an otherwise clinician, what is your population need, what information would be helpful for you to treat your patients better. If you start from that and start writing down, okay, if I knew these data points, right, if I knew the percentage of my patients aged 18 years or older, that we're seeing within 12 months, that I'm treating for chronic conditions just to make sure they're coming in regularly. Having regular data, that would be really helpful to me, that's a starting point. In my experience, working with clinicians to start from that point of what information do I need, take much better categories and outcomes than those that just try to go down the list and say what are going to be the easiest to report. If it's not helpful information to you, you're just going through the motions and checking a box. And it's not going to help you actually move as more things get weighted towards the improvement activity.

So how you actually go about reporting, there are several different collection types, there's different ones that actually do the collection for you that is based off of claims data, other parts you have to do more. This is why it's important to do that gap readiness assessment to figure out where you are and what are you going to be able to report especially based off of where you are on your EHR system, and what kind of information you can pull. One of the benefits of this right now for being a small and underserved rural practice is that you do get bonus points that automatically go into your score. So if you're a small practice, you do get three points in the quality performance category for measures that don't meet complete requirements. And if you can provide the complete information for quality performance category and if you submit at least one quality measure, you automatically get six bonus points. So in thinking about that, you have those three different performance categories under quality that you could do. If you can meet these, you automatically get bonus points, which are really helpful for getting that payment adjustment.

Another part of it is keep in mind that each of the different categories have different weighting within themselves. And so whether or not something is a medium weighted activity or a high weighted activity can also get you extra points. So if you're a small practice and you can get double the points for the activity that you submit, and keep in mind when you go down the checklist, there's something that'll say, "okay, if you do this quality requirement, it's worth two points. If you do this one, it might be worth six," and since it's a small practice, you can get double the points for those medium and high weighted activities, you might be strongly encouraged to focus on those types of activities that you can impact rather than ones that might be easier to report but give you very few points. And you only have to do, and this is the improvement activity section. Under the improvement activity, this includes stuff like having extended hours for your practice, having call available 24/7 like a number to dial into. You only have to do two of those activities. But right now that number will be increasing going forward.

Moving on, we're going to talk about what's called the PI or the promoting interoperability performance category. Again, this is the new evolution of meaningful use. So many of you have heard about this, you might have gone through an EHR conversion nightmare, many of you. And so in here, to be able to promote PI, it is very similar to what we have done for meaningful use, but they're wanting to see that you're using your EHR more thoughtfully. So there are six required measures in addition to what you were previously doing in your stations for meaningful use. Under these categories, this is your e-prescribing, your provider-to-patient exchange, your health information exchange, and your public health and clinical data exchange. So having these in EHR, we're trying to move from an EHR that just gives you data to one that is actually interoperable with other EHR systems, especially, like from an e-prescribing, what's going to the pharmacy. That's one of the failures that happened with EHR that this is trying to address. In order to be able to report all the different pieces under the PI performance category, you do have to collect the data for a minimum of 90 continuous days. Using specifically the 2015 Edition of CEHRT, or you can submit a hardship application. I do have practices that are still on paper, so they automatically assume that they want to submit the hardship exemption to being able to have this category. I will say that works for a period of time, but given the direction that we're moving, you need to look at where you are from a capital investment standpoint and how much longer you can kick that can down the road before you actually do this. Because when you have this reweighted to zero percent, that means the other areas are weighted more heavily. So when we think about cost, which you don't have a ton of control over, that gets additional weight. Quality, you do have a great amount of control over and the improvement activities you might have a control over, but when it's reweighted on quality, quality is eventually going to be coming down and the improvement activity is expected to go up. And improvement activities are constantly reset each year, so you can't do the same improvement activities over and over and over again just because you have extended hours. Once you've done that, you've done that improvement, and they expect you to maintain that and you pick two new ones each year. So keep in mind even if you meet one of these hardship exemptions for the promoting interoperability performance, say you are still on paper or maybe your system is not up to snuff to be able to do it, you don't have sufficient internet connectivity, look into what kind of investments or help that you need to be able to get that where you don't stay in an exemption application constantly.

This slide shows all the different areas for the hardship exemption application, as I mentioned, insufficient internet connectivity if you're a small practice, if you were using a decertified EHR technology, a lot of people made investments that one’s ended up not actually meeting the meaningful use criteria. So, think about, all right, I have this now, but how much longer do I want to be able to fill out this exception application, since you do have to fill it out every year and you want to move towards where is this going. Keep in mind, there's different policies for RHCs and FQHCs. Most of the ones that I'm working with have fallen under the exemption from MIPS, and the reason for this is because of that cost-based reimbursement that falls for RHCs and the different grants for FQHCs. So being able to make a payment adjustment to the Medicare fee schedule, if you're not having the physician fee schedule actually apply to your practice because you have that set rate, visit rate, under the RHC cost reimbursement model, it's not really applicable. So that's why a lot of them get exemption. However, if you're under a critical access hospital and you're assigning your rights over the critical access hospital, you may still qualify for being able to do MIPS if your Medicare Part B services are actually paid under this way. So some groups, not all of their services, are falling underneath that RHC cost-based

reimbursement piece of it and they can actually apply for having them. And this will actually help them move along that APM model if they're not in that all-inclusive rate that they have for the RHCs. The low volume billing threshold still applies, so if that is the case then even if you're an RHC and/or an FQHC, and you have payments under the physician fee schedule, if you're well below that minimum threshold, you still get exempted from MIPS.

If for those of you that I said if you have actually assigned your billing rights to a critical access hospital, your payment adjustments only applies the method to co-payments. They're not specifically for your practice. If you're method one, then that payment adjustment applies anything from the professional fee side of things, but that facility payment is still under that cost side and you don't have that MIPS adjustments. So when we think about, okay, there's going to be a positive or negative adjustment, make sure you're applying it, and when you're thinking about what investments should I be making for this, make sure you're doing your math correctly. It only applies to certain buckets if you are working with a critical access hospital. And so finally, we've provided for you this performance and quality improvement documentation of worksheet that has all the different specific measures for CLL. So going through that, seeing what are the different quality measures are on here that are applicable to you that are going to be easiest for you to report but more importantly, what is going to be most meaningful for the quality of care that you're providing to your patients, so going through this worksheet will be really helpful for you to be able to figure out specifically what are the quality metrics I can both get my MIPS credit for that are meaningful for CLL. And then the other piece of it is that worksheet also has the improvement activities performance category. It has the link specifically to looking at the different activities that are online, the improvement activities inventory, and selecting which ones are relevant to your practice. You may already be doing certain things and have never reported on them, that's great. You can report those for year one, but going forward, you need to be thinking about what are the other improvement activities are on here that I can plan for, for the next year.

So hopefully this information, I know it was kind of like drinking from a firehose because there's a lot of information on here, so with that being said, we thank you for your attention. Hopefully this information was helpful.