



## COLORADO DEPARTMENT OF HEALTH CARE POLICY & FINANCING

### **Benefits Collaborative Public Meeting: Non-Prenatal Genetic Testing**

Wednesday, October 16<sup>th</sup>, 2013

3:00 p.m. – 5:00 p.m.

225 E 16<sup>th</sup> Ave., Denver CO 80203

1<sup>st</sup> Floor Conference Room

#### **Agenda**

<b>Time</b>	<b>Topic/Agenda Item</b>	<b>Responsible</b>
3:00 – 3:10 p.m.	Welcome and Introductions <ul style="list-style-type: none"><li>• Ground Rules &amp; Phone Etiquette</li><li>• Staff Contact Info</li></ul>	Kimberley Smith
3:10 – 3:20 p.m.	Benefits Collaborative Overview <ul style="list-style-type: none"><li>• Purpose of the Benefits Collaborative</li><li>• Review the role of participants and the Department</li><li>• Parking Lot List</li></ul>	Kimberley Smith
3:20 – 4:40 p.m.	Review and Discuss Draft Coverage Standard	Ana Lucaci Chris Acker
4:50 – 4:55 p.m.	Roadmap Moving Forward	Kimberley Smith

#### **Facilitators:**

- Kimberley Smith, Benefits Collaborative Manager, Department of Health Care Policy & Financing (HCPF)
- Ana Lucaci, policy specialist, HCPF
- Chris Acker, policy specialist, HCPF

#### **Welcome**

Kimberley Smith, Benefits Collaborative Coordinator introduced herself and asked participants in the room and on the phone to introduce themselves.

Kimberley informed the group that these proceedings are open to the public and recorded/transcribed. Any information provided (including name, other demographics, Medicaid enrollment, and any other protected health information) will be considered to be public record and not confidential.

Kimberley then reviewed the ground rules for the meeting, they include:

- Tough on issues, not people

- One person speaking at a time
- Be concise/ share the air
- Listen for understanding, not disagreement
- Speak up here, not outside
- In the room: Phones on silent/vibrate
- On the phone: Please mute your line
- Please introduce yourself when asking a question or making a comment

## **Benefits Collaborative Overview**

Kimberley Smith provided her contact information ([Kimberley.Smith@state.co.us](mailto:Kimberley.Smith@state.co.us) 303-866-3977) to which participants can address their future questions and suggestions.

She then briefly reviewed the concept of a Benefits Collaborative. She explained that the purpose of the Benefits Collaborative is to create a benefit coverage standard, which is the term the Department uses to refer to a benefit policy.

Kimberley explained that all benefit coverage standards must:

- Be guided by recent clinical research and evidence based best practices
- Be cost effective and establish reasonable limits upon services
- Promote the health and functioning of Medicaid clients

Kimberley then reviewed the role of participants and the role of the Department within (and between) Benefits Collaborative meetings. The collaborative exists to assist the Department in making informed decisions by contributing in the following ways:

- Share diverse perspectives to expand understanding ahead of decision making
- Share new information/research
- Ask questions and provide informed insight in response to analysis offered and suggestions made

Kimberley invited participants to make the Department aware of any studies or research which we may not have seen and to speak from their own experience of best practices.

In turn, The Department will:

- Work with participants to ensure that concerns are consistently understood and considered
- Wherever possible, work to ensure input is reflected in alternatives developed; and
- Provide feedback on how public input influenced decisions made and explanation when input cannot be incorporated/adopted

Kimberley reminded participants that any unanswered questions and all suggestions made will be tracked in the [Listening Log](#) posted online and that each question/suggestion will receive a response from the Department.

Kimberley then gave the floor to Ana Lucaci and Chris Acker, policy specialists, who walked the group through each section of the proposed draft benefit standard, for discussion.

## **Discussion**

Ana explained that the draft benefit coverage standard was created for the Department by a group of specialists at the Center for Evidence Based Policy at the Oregon and Health and Science University. The draft proposal consists of their recommendations for Colorado Medicaid.

Ana then asked the group, who had a chance to review the draft ahead of the meeting, if there were any questions or comments related to the Brief Coverage Statement section of the draft standard. None were offered.

Ana then asked the group for any feedback on the Services Addressed in Other Benefit Coverage Standards section. None was given. Ana pointed out that, presently, prenatal genetic testing is mentioned in the Maternity Benefit Coverage Standard, which will be reviewed soon. Ana encouraged those with questions about prenatal genetic testing to make a note of them and they will hear from the Department on this issue soon.

Ana proceeded by opening up the floor to discussion around the Eligible Providers section. Ana reminded individuals that these recommendations were provided by the Vendor, who looked at policies in other state commercial, Medicaid and Medicare plans.

COMMENT – Kate Crow, genetic counselor with Centura Health, noted that the providers listed in this section have specific genetic training but she wonders if, in the case of cancer genetic counseling, ordering providers (including physicians and nurse practitioners and PAs) who are not geneticists but who have taken an intensive credentialing course in genetics, such as the City of Hope intensive cancer genetics course out of California, may be eligible. Kate believes this course to be a pretty good alternative to getting an advanced degree in genetics and can confer credentials on folks who don't have degrees.

QUESTION – Kelli Swan, with the Colorado Cancer Coalition (CCC) Genetics Task Force, sought clarification based on Ana's earlier statement, was Ana saying that Medicare also follows this policy?

RESPONSE – No, Ana merely meant to state that the Vendor researched what, if anything, commercial plans, other state Medicaid programs and Medicare do (or do not) cover, before providing their recommendations. Ana took this

opportunity to point out the North Carolina has a similar provision that eligible providers consist of certified geneticists only.

Kelli Swan agreed and underscored that any provider that meets Medicare guidelines can order a genetic test. Clarification – Any provider can order a genetic test. As long as the patient meets Medicare's coverage criteria, the test will be covered for Medicare patients. No restrictions on the type of provider that can order testing.

COMMENT – Serenedy Smith, genetic counselor and medical policy specialist with Myriad Genetic Laboratories, who specializes in managed care, added that she sees lots of different types of insurance plans and the vast majority of both commercial and government plans across the nation don't require a specific license in genetic counseling. She offered Texas, Oklahoma and California Medicaid as examples. She ended by stating that the criteria in the Colorado standard is certainly not the norm across the nation.

COMMENT – Annie Lee, Director of Medicaid and Subsidy Programs at Kaiser Permanente, agreed with Serenedy's comment and added that Kaiser has discussed genetic training for physicians around cancer genetic testing but, for diagnostics, Kaiser does have physicians without genetic training ordering those types of genetic tests.

COMMENT – Dr. Douglas Aptekar stated that, it is one thing to test patients after cancer but, as a primary care OBGYN, he would like to be able to identify patients prior to being affected. When he takes a patient history and finds one who has a profound family history of individuals who are no longer living, he would like to test unaffected individuals. He deals with genetics every day with every OB patient he sees and doesn't need a genetic counselor to order testing for Cystic fibrosis or Down syndrome. He would object to being required to undergo specialty training in order to order a specialty test for breast cancer screening or Lynch syndrome. It is an unnecessary obstacle to providing care.

RESPONSE – Annie Lee with Kaiser Permanente concurred.

Ana asked Dr. Aptekar if he provides counseling after the test also.

Dr. Aptekar said absolutely. He is also obligated to counsel those patients who test negative for the BRCA gene but who may still be at high risk for breast cancer to do other kinds of screenings like whole breast ultrasounds and MRIs and, without doing so, his malpractice carrier holds him responsible for not testing those patients appropriately. He continued that, when looking at breast cancer genetics, if someone is appropriate to test for the breast cancer gene and the physician follows NCCN Clinical Practice Guidelines (NCCN), the negatives require just as much counseling as the positives.

Kimberley Smith noted that she did receive one email from a stakeholder who believes genetic counseling should be part and parcel of any genetic testing. She asked if there was anybody in the room who supported the Eligible Provider section as it is currently written.

COMMENT – Dr. Aptekar agrees that genetic counselors should be on the list of eligible providers but noted that the question is really “who can provide it?” As a primary care OBGYN he is extremely interested in the quality of care for his patients and having access to breast cancer genetic information, he feels he is fully qualified to do that counseling.

QUESTION – Kate Crow, genetic counselor, is concerned about the possibility of people not being evaluated for all the possible inherited risks for breast cancer. Is there some way that we could assure that more than one gene is assessed, since we know that there are several?

COMMENT – Christine Barth, genetic counselor with SCL Health Systems, agrees that genetic counseling needs to be provided and also agrees that there are many providers who are not certified genetic counselors who provide a quality service, however, the dilemma seems to be how to determine which providers meet the minimum criteria for providing the counseling appropriately. She postulated that Dr. Aptekar may have voiced what is a minority (unheard) among some providers and again stated that she is not sure how we can determine which providers have the necessary skill base and interest to provide these services at an appropriate level.

RESPONSE – Dr. Aptekar responded that is what they always do. He is not going to embark on an operation that he does not know how to do. The educated providers (including physicians and nurse practitioners and, particularly, OBGYNs) who often are obligated to deal with breast health should be able to self-determine that they understand and should order this test.

COMMENT – Kami Schneider, with the University of Colorado and Children’s Hospital, noted that, speaking as a tax payer, she knows that studies are still being done but recent data appears to suggest that when a none-genetics provider is involved the tests are ordered inappropriately about 20-40% of the time and that there are increased costs associated with this. While she agrees with everything said above, as a tax payer, she is not in favor of excess costs. That said, she does believe in access to care. If this criteria presents a barrier to patients who are qualified getting the services they need, that is a problem.

RESPONSE – Serenedy, believed that the data Kami is referring to was published by a laboratory and asked Kami if this was correct.

Kami could not point to a single author but said she had heard of multiple studies at the national conference, from which she had just returned.

The study that Serenedy knows of that Kami may be referring to was a white paper published by a genetics reference laboratory, which provides genetic testing for a multitude of conditions, including vary rare genetic syndromes. Myriad also published their own white paper recently, based on their data, which is specific to just hereditary breast and ovarian cancer syndrome and Lynch syndrome (the two most common hereditary cancer syndromes with well-established guidelines, most providers look toward NCCN to test appropriately). Myriad found that 93% of tests that come through their door are clinically appropriate test orders. Serenedy wanted to underscore that, when discussing the two most common hereditary cancer syndromes, providers (of all provider types) do a good job.

Kami pointed out the draft benefit coverage standard under discussion is for all genetic tests, not just hereditary cancer tests – hence her concern.

Ana stated that she welcomes any evidence based research, such as the white papers discussed, which the Department’s internal team is happy to review.

COMMENT – Kelli Swan, with the CCC Genetics Task Force, stated that we all want tests to be ordered appropriately, which is why it is important to review the guidelines that are forthcoming. If the patient (unheard) meets U.S. Preventive Services Task Force (USPSTF) or NCCN guidelines that is an appropriate test, so developing that criteria is one way to ensure that tests that are ordered are truly appropriate tests.

COMMENT – (Unattributed) In light of what everyone is saying, I agree that limiting appropriate providers may cause some difficulties down the road, especially if we are thinking outside of the box and not just about cancer genetics. As genetic testing becomes more popular, more providers are likely to want to provide it.

COMMENT – Annie Lee with Kaiser Permanente wondered if there is a distinction that can be made that draws a line between diagnostic genetic testing and cancer genetics, that does tend to require a little more specialized knowledge.

RESPONSE – Kami stated that, when she reviewed the draft coverage standard, she was struck by the clear guidelines that were present for certain tests and the absence of guidelines for most tests. Kami suggested that the standard be offered and then exceptions be given for certain tests that meet certain criteria.

COMMENT – Carol Walton, genetic counselor with the Children’s Hospital of Denver, who works in pediatrics, thinks that, as written, the draft standard seems to preclude a non-genetics medical provider from being able to order a diagnostic test, such as a

micro-array on a newborn with multiple congenital anomalies and that would be very problematic because those babies would not come to the attention of a genetic service until sometime after the newborn period.

Ana noted that the conversation was moving towards services and suggested that a review of the algorithm in the Covered Services Section may speak to some of the above concerns. Kimberley assured the group that all questions and suggestions were being recorded and will receive their due consideration.

Ana asked for any final comments with regards to the Eligible Providers section of the draft benefit coverage standard.

COMMENT – Serenedy pointed out that there are resources that detail the process of informed consent for genetic testing with patients. Perhaps it's more appropriate to focus on informed consent and going through the steps of the process with patients rather than provider types.

Ana opened discussion on the Eligible Places of Services section of the standard. Hearing none, she moved on to the Eligible Clients section.

COMMENT – Christine Barth, genetic counselor, stated that she has often seen pregnant women for BRCA testing, so it isn't really appropriate to say "any non-pregnant client".

RESPONSE – Ana noted this as a great comment. Kimberley postulated that this possibility may be covered in the maternity standard but that the team will certainly check.

Christine was not sure that the maternity standard did cover this. Ana stated that, because the maternity standard is under review, there may be opportunity to add it in that standard, this one or prenatal.

Ana then opened discussion on the Covered Services and Limitations sections. Ana pointed out that, on page two of the draft standard, are listed a series of tests that the Vendor suggested be covered; this does not mean that these are the only tests that would be covered.

COMMENT – Kate Crow, genetic counselor, is uncomfortable with the word "algorithm" because, as written, it does seem as though the only two tests that the standard is concerned with are the tests detailed on page two. When asked by Kimberley to clarify, Kate explained that it may appear to non-specialists that colorectal cancer and BRCA testing are the only tests covered. The algorithm also seems very narrow. She then apologized because, looking at the standard one page at a time, she finds herself a bit confused by the purpose of the algorithm.

RESPONSE – Kimberley, deferred to Ana Lucaci and Chris Acker, to provide a definitive answer on behalf of the Department but explained that, as she reads the standard, a provider can use the algorithm on page three to determine whether a whole series of genetic tests may be appropriate for a client and that, on page two, the authoring Vendor singled out specific services that should always be provided and do not need to be determined appropriate by using the algorithm. She suggested, perhaps, switching the order so that the algorithm appears on page two and the covered services on page three.

Ana agreed with this assessment.

COMMENT – Kate Crow, genetic counselor, then commented on the algorithm itself by pointing to the statement that “pretest genetic risk assessment and/or clinical evidence indicate chance of genetic abnormality is greater than or equal to 10%”. Kate stated that some people have a less than 10% risk but it really looks like something is going on in their family and they need testing. Also there are not risk calculators for most genetic tests at present.

COMMENT – Autumn Tansky, genetic counselor, on behalf of the CCC Genetics Testing Task Force. The 10% probability number is a very poor number not applicable in most situations. Currently, what she and colleagues would like to recommend on behalf of the Task Force (which represents physicians, mid-level providers, patients and genetic counselors across the state – in consensus) using NCCN guidelines. These guidelines are created as a national standard and updated annually. This provides, not only criteria for BRCA and Lynch syndrome (which are outlined on page two of draft standard) but also rare cancer syndromes as well. It is absolutely not complete so the standard would need to include what to do when a test is not outlined in the guidelines.

Autumn further noted that the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) 2009 and USPSTF 2005 guidelines used in the draft benefit coverage standard are quite old in the world of genetic counseling that evolves very quickly. The Task Force recommends using the most updated guidelines within a given year and for that to be re-evaluated annually, as the various NCCN guidelines are updated.

Additionally, NCCN is very clear and the Task Force encourages that the standard Colorado develops have the same clarity of coverage for, not only affected but also unaffected, patients with no personal history of cancer but with a family history. She reiterated Dr. Aptekar’s point that not everyone has access to their family history and should be able to access testing.

The final sentiment of the Task Force, is to encourage that there be a clear appeal process with opportunity to submit additional evidence based criteria.

RESPONSE – Chris Acker, Department policy specialist, pointed out that, in the Prior Authorization section on page five, it states that all genetic tests will require a prior-authorization request (PAR). Through that process there is an appeals process and other processes that ask for evidence of medical necessity. There is certainly the opportunity to make the case as to why a client may need something.

This algorithm is meant to help providers ask themselves, “might this be covered?” and also to provide an example similar to the process the authorizing Vendor (made up of medical professionals) will use.

The Department’s Chief Medical Officer, Dr. Judy Zerzan may also speak to the history of how and why this policy and algorithm has thus far been drafted as it has been drafted. We can make changes to the policy, pieces can be moved around as part of the continuing review process.

COMMENT – Christine Barth, genetic counselor, spoke more to the 10% provision mentioned above. There are no models for 99% of the tests she runs. If you refer back to EGAPP and USPSTF documents, and specifically USPSTF, in relationship to the ACA language, they have clarified the high risk status of patients is determined by the health care professional, having done appropriate health and medical record research and review. There is no specified number cut-off for testing but, rather, leaving it to the professional to determine high-risk patients. Christine suggests that, if the Department uses EGAPP and USPSTF as a reference later on, it reflect this policy.

COMMENT – Dr. Aptekar made the comment that he doesn’t use 10% risks for anything in his practice. As an obstetrician he uses a 1% risk or less. He conducts annual pap smears on patients that are at 1 in 1,000 risk. The reality is that he offers Cystic fibrosis testing, Down syndrome testing for people that are pregnant; it is about their perception of the risk. When he sees a patient whose mother had ovarian cancer and is deceased, if that ovarian cancer risk was 20%, the patient knows she has a 10% risk, that’s great. However, there are people with much lower numbers that are low risk but high burden; if you are the one who carries that risk, the burden is very high for you. Dr. Aptekar stated that, if he can diagnose and prevent one patient from developing ovarian cancer, that is a great savings to the community at large.

Dr. Aptekar then excused himself from the call by thanking the Department for convening these meetings and listening to individuals “on the front lines”.

COMMENT – Unattributed individual stated that, of the 10% criterion mentioned above, her understanding is that it comes from one article once in the 90s and then got carried over arbitrarily ever since. She does not know of any data that supports using that as a cut off.

COMMENT – Serenedy stated that it was something taken from an American Society of Clinical Oncology (ASCO) statement out of context and, in a subsequent statement, they took it out and made clear that they do not advocate 10% be used as a threshold for any testing. Serenedy offered to provide the Department with both ASCO statements.

COMMENT – Unattributed individual commented, for perspective, that some of these syndromes are pretty rare and have a less than 1% chance of having one of these. When you have a family history, it may bump it up to 3% or 5%, so 10% is huge.

QUESTION – Unattributed individual commented that she is unfamiliar with the ACCE, Analytical and Clinical Validity Criteria (referenced in the proposed algorithm), and is not sure she could sit in her office and put it to use as currently suggested in the standard. She asked if any other clinicians in the meeting was familiar with this criteria and would feel comfortable using it.

RESPONSE – Ana stated that these questions are posted on the CDC website under ACCE. She also pointed out that the proposed algorithm includes only the analytic and clinic validity criteria. She pointed out that, in the algorithm, it states “and/or the tests recommended by EGAPP or USPSTF”. She ended by stating that, at the moment, she cannot speak on these questions in the ACCE model.

Kimberley handed out some ACCE questions in the room and has uploaded the document to the Benefits Collaborative web site as “Appendix A”.

Autumn Tansky with the CCC Genetic Testing Task Force asked how to interpret the Appendix A document. It isn’t clear how to use the content of Appendix A as determining criteria.

Ana promised to look into the answer.

Serenedy asked, as a follow-up, would the Department be requiring a provider to provide and answer to these many questions? Second individual confirmed that, such an expectation, would prohibit clinicians from seeing very many patients (too much work).

Ana said it may simply be that, after reviewing the criteria, the provider provides a final attestation of consent. She also postulated that it might make sense to say “EGAPP or USPSTF” first and then go to ACCE questions if not otherwise covered.

Kimberley confirmed that there needs to be more direction around how to use the ACCE tool.

Unattributed individual also noted that very few tests have been evaluated by USPSTF or EGAPP. This comment was seconded on the phone by an individual who stated 99% of tests probably have not been evaluated by USPSTF or EGAPP.

Kate Crow added that testing is expanding at a rapid rate. We need to be flexible enough in whatever we do that it can accommodate all of these new developments.

COMMENT – Kate offered the separate comment that, as genetic testing becomes for routine, costs will lower.

QUESTION – Kami Schneider with the University of Colorado notes that, in the Further Requirements section, it states “Patient or surrogate must consent to genetic testing.” She asked what that would look like. Would it be written consent? Usually providers don’t have to get written consent. It would be nice if that was clarified.

COMMENT – Carol Walton with the University of Colorado, revisited the section that states “the results would impact health outcomes for patients or patient’s first degree relatives in one of the following ways...” and noted that one of the questions many families ask her team is about the recurrence risk for their future children or other family members. She is not sure, based on current wording, how broadly the interpretation of change treatment would be applied in that case. For example, they may see a child that they recognize may have a genetic syndrome and may even have a clinical diagnosis but genetic testing of that child would provide information about the specific mutations causing conditions in the family – useful information for future counseling and testing (for example, identification of carriers, prenatal testing).

COMMENT – Kami Schneider added that reproductive information should not be limited to first degree relatives.

COMMENT – Autumn Tansky with the CCC Genetic Task Force pointed out that EGAPP has published several documents with regards to Lynch Syndrome and genetic screening and testing and she wants to be sure that this is referring to germline genetic testing and that diagnostic germline genetic testing would be a covered benefit for Colorado Medicaid (not simply genetic screening via a tumor test).

QUESTION – Darcy Huisman, genetic counselor with the University of Colorado asked about the section before Further Requirements, indicating that pre-test and post-test evaluation in genetic counseling are covered after meeting the requirements above. She was unclear as to whether she understood that section appropriately. In her clinic, evaluation is done before testing and waiting until after test would not be appropriate. She asked for further explanation.

RESPONSE – Kimberley explained that, the way she reads it as a consumer, the person providing the testing must be equipped to provide both pre-test and post-test counseling in order to be considered eligible to perform a test.

Ana agreed.

Chris Acker then walked everyone through the special provision recently added to page 4 of the draft, concerning Early and Periodic Screening and Diagnostic Testing (EPSDT). He read the provision out loud, for the benefit of those on the phone who may not have had it in front of them. The provision can be found in draft on the web site under the “Handouts” column).

QUESTION – Sam Murillo with Family Voices asked if providers need to cite language specific to this provision when asserting that a treatment is medically necessary for a child or can they just write an impact statement? It is not uncommon for the determining Vendor, APS, to tell the providers they need to submit additional documentation because this letter of medical necessity is not complete.

RESPONSE – Chris recommended that any provider state, to the best of their ability, why they believe it is something that should be covered, whether in an initial PAR or as part of an appeal. Providers should have clinical evidence to back up medical necessity and it doesn't hurt to say “in my professional opinion, this falls under the provision of ESPDT.”

Ana moved the conversation forward to the Non Covered Services and General Limitations. She noted that, in an earlier draft of the standard that was emailed out to the group, there were only four tests identified in this section. A fifth has been added, concerning diagnosis of Autism. It reads:

*Routine genetic testing for the diagnosis of autism; genetic tests can be considered, as recommended by a regional genetic counselor, if there are specific dysmorphic features, congenital anomalies and/or evidence of intellectual disability.*

QUESTION – Sam Murillo is currently working with Department and partner organizations on positive systems change related to the topics of Autism and EPSDT. Sam asked if he should be reading the addition to mean that individuals with intellectual disability would not be able to get a genetic test that they would qualify for.

RESPONSE – Kimberley noted that “routine genetic testing for the diagnosis of autism” is the non-covered service and that the language that follows highlights exclusions, meaning they would be covered.

Sam asked that the language be changed to better clarify the distinction. To honor true person-centeredness we should make the language as clear as possible.

Ana agreed to revisit the language.

COMMENT – Carol Walton, genetic counselor, suggested that the Department consider adding family history to the list of exclusions that include: specific dysmorphic features, congenital anomalies and/or evidence of intellectual disability. Clinicians would be more suspicious of an identifiable genetic cause of Autism if a close family member already had that diagnosis.

COMMENT – Kate Crow, genetic counselor, jested that most genetic counselors may pay the Department money to add an item to the Non Covered Services section – Methylene tetrahydrofolate reductase (known as MTHFR) testing (for thrombo embolism).

RESPONSE – Kimberley asked if others felt similarly.

Kami Schneider agreed.

Christine Barth also agreed.

COMMENT – Kami revisited the discussion around who the order providers should be. She suggested that we focus on appropriate testing being offered with appropriate counseling. She thinks about people who may not be qualified to order appropriate tests and people who may not seem as qualified who do order appropriate tests. It may be best not to focus on type of provider but, rather, that appropriate tests are done with proper informed consent.

She also suggested the Department consider tiered testing, instead of all-at-once testing.

RESPONSE – Kelli concurred with Kami's comment. Focusing on appropriate testing and what informed consent looks like, does a better job impacting quality of care than putting restrictions on the provider who orders it. There is a lot of literature out there that ordering tests are within a physician's scope of practice.

COMMENT – (Unattributed) USPSTF actually says that, with regards to BRCA testing, multiple provider types can order tests. She is concerned that the Department may be looking at some but not all of the USPSTF's guidance.

Kimberley thanked everyone again for the collaboration and information exchange experienced in the meeting. Ana moved the conversation on to the Prior Authorization Requirements section.

COMMENT – Carol Walton with the University of Colorado, in thinking about prior-authorization, thinks about services that need to be provided in an acute setting for the purpose of medical management, as in the case, for example, of diagnostic testing for a newborn. Also, she wonders about families traveling, for example, from great distances and having to do so more often due to separate PARs. She wonders if there are certain “no-brainer” situations that can be spelled out that would not require a PAR.

RESPONSE – Chris Acker state that he and Ana have to go back to the Vendor and review the algorithm they use and their best practices to see if some of these questions and suggestions, that have been brought up today, are and/or can be addressed through the Vendor’s best practices.

COMMENT – Kate, stated that Carol has to deal with things that are a little more immediate than other geneticists and genetic counselors. Kate has some trepidations about urgent situations and appeals processes and she would feel more comfortable with the PAR process if the appeals process was communicated clearly to them.

RESPONSE – Chris responded by saying that, being that we are working in a new and evolving area, we want to be sensitive to tax payers and make sure we are appropriately managing funds. It may be that, over time, we see that a particular test or situation has never leads to a denial and we may revisit PAR at that point.

COMMENT – Carol Walton revisited the section of the draft that refers to “genomic profiling to assess cardio-vascular risk”. She suspects the phrasing comes from EGAPP and refers to risk for common atherosclerotic type heart disease. She asks that the wording of that be looked at carefully because there are a number of single gene conditions that impact cardiovascular risks in other predictable and treatable ways. For example, Long QT Syndrome and a number of others. She would not want some of those tests excluded by misinterpretation of very general language.

QUESTION – Sam Murillo asked if providers can utilize the PAR process to serve as an advocate to expedite coverage of a medication that is relevant to after-screening (so that the client shows as active on Medicaid when they go to the pharmacy).

RESPONSE – Chris Acker said no, because PAR for pharmacy are handled by a separate Vendor and live in a different system than medical PAR. He offered to

take Sam's information and examples to work further, outside of the scope of this collaborative, on access issues to pharmacy medications.

Sam thanked him because need for expedited medications is common.

Kimberley thanked everyone for attending and encouraged the group to follow up with her via email or phone with further questions and comments. She noted that there may be a second meeting, depending on the size and nature of revisions made. She assured the group that a revised standard would be sent to them and that they will have further opportunity to comment on draft revisions as the standard progresses through the Benefits Collaborative process.