LDH Managed Care Policies Procedures Public Comments

Date Submitted	Item Number and Policy	My question/comment
11/20/2021 18:31	2021-LDH-12 MCO Manual > Part 4: Services > Medical Transportation > Ambulance (Proposed effective date = 12/27/2021)	The Louisiana Ambulance Alliance ("the Alliance") appreciates the opportunity to comment on the recently proposed changes to the MCO manual affecting ambulance transportation in Louisiana. The Alliance is the membership organization for EMS providers in Louisiana. From Acadian Ambulance, the state's largest EMS provider, to Caddo Fire District #6, one of the state's smallest providers, we speak with one voice. For the reasons detailed below, we urge the Louisiana Department of Health adopt the following suggestions and revise the proposed MCO manual provisions posted on October 7, 2021. 1. Treatment-in Place Ambulance Services Provision: "Each paid treatment-in-place ambulance claim must have a separate and corresponding paid treatment-in-place telehealth claim, and each paid treatment-in-place telehealth claim must have a separate and corresponding paid treatment-in-place ambulance claim or a separate and corresponding paid ambulance transportation claim. The MCO may not reimburse for both an emergency transport to a hospital and an ambulance treatment-in-place service for the same incident." (Treatment-in-Place section, pg. 2) Comment/Recommendation: This type of procedure can be unfair to the parties connected to these types of services. Each healthcare provider is at the mercy of an unconnected provider to correctly bill for the claim. An ambulance provider and a practitioner can perform a service but never be reimbursed for their services due to the fact that one of the parties does not bill for the service or does not bill correctly for the service. If ambulance

		treatment-in-place claims and treatment-in-place telehealth claims are not both submitted, there should be an avenue for a party who renders services to be paid unilaterally without relying on the other party's billing. Out-of-hospital care reports/documentation could be reviewed to determine if a telehealth visit had in fact taken place if necessary for a provider to be unilaterally paid for their services. If the payment procedures are not changed, then the language used in this paragraph needs to be clarified. The provision states that there must be a paid ambulance claim and a paid telehealth claim for both practitioner types to be paid for the telehealth treatment-in-place services. If neither can be paid until there is both a paid ambulance claim and a telehealth claim, then it seems like Medicaid/MCOs would never be able to make a payment because one has to be paid in order to have the other paid. The recommendation would be to state that each submitted and payable treatment-in-place ambulance claim must have a separate and corresponding submitted and payable treatment-in-place telehealth claim, and each submitted and payable treatment-in-place telehealth claim must have a separate and corresponding submitted and payable ambulance treatment-in-place claim or a separate and corresponding submitted and payable ambulance transportation claim. 2. Treatment-in-Place Ambulance Services Provision: "The MCO shall require ambulance providers to submit pre-hospital care summary reports to prevent payment of treatment-in-place ambulance claims and emergency ambulance transportation claims for the same occurrence." (Treatment-in-Place Ambulance Services section, pg. 3-4) Comment/Recommendation: This new provision is a bit concerning. It can be interpreted

		that an ambulance provider must submit pre-hospital care summary reports for every emergency ambulance transportation claim submitted. It is unclear if it applies to all ambulance transport claims or just those claims where there is an ambulance treatment-in-place claim and an ambulance transport claim submitted for the same beneficiary on the same date of service. It would be an enormous administrative burden on providers to submit out-of-hospital care summary reports for all claims submitted to MCOs/Medicaid. Can you please confirm that this language is not intended to cover all emergency transports? Our recommendation is that clarifying language should be added which states that pre-hospital care summary reports will only be requested and are only necessary if there is a treatment-in-place claim submitted by the ambulance provider on the same day and for the same beneficiary as an emergency ambulance transportation claim. The language used should not allow for an interpretation that out-of-hospital care documents need to be submitted with every ambulance claim. 3. Non-Emergency Ambulance Transportation Provision: “Refer to the Non-Emergency Medical Transportation section of this Manual for additional transportation requirements that apply to both NEMT and NEAT.” (Non-Emergency Ambulance Transportation section, pg. 4) Comment/Recommendation: As stated in previous comments, there should not be a reference contained in the ambulance section to the NEMT section. All ambulance provisions should be included in the ambulance section. NEMT providers and ambulance providers are two separate and distinct provider types which are required to follow separate and distinct law, rules, etc.

		It is recommended that all the provisions which pertain to non-ambulance providers be placed in the NEMT sections of the manual, and all ambulance provisions should be included in the ambulance sections of the manual. This change would ensure that there is no confusion about which rules apply to which program. 4. Air Ambulance Provision: "Fixed wing transports must be prior approved by the MCO." (Air Ambulance section, pg. 5) Comment/Recommendation: This policy directly conflicts with Health Plan Advisory (HPA) 17-16. The HPA states "Authorization is required for emergency air ambulance transportation services; however, the authorization process should be done during a post payment review and not prior to service delivery. MCOs should receive and review claims for payment for emergency air ambulance transportation services retrospectively. LDH is currently in the process of updating applicable provisions of its State Plan Amendment, Rules and provider manual in order to clarify this requirement." The process contained in this HPA should be followed, and all necessary changes which are mentioned in the HPA should be made if they have not been already made. The proposed provision could be interpreted to require a prior authorization on emergency fixed wing services. In an emergency, time is of the essence and any delays in providing care and getting patients to the most appropriate medical facility could lead to negative

		impacts/outcomes on patients being treated. Thus, the recommendation would be for the language stating "fixed wing transports must be prior approved by the MCO" be deleted and the language from the HPA be adopted in the MCO manual. Authorization may be required, but the process should be done during a post payment review and not prior to the delivery of a service. 5. Ambulance Transportation Modifiers Provision: "Emergency ambulance claims, that are not treatment-in-place, are only payable with a destination modifier of H, I, or X. Valid treatment-in-place ambulance claim modifiers are identified in the Treatment-in-Place section." (Ambulance Transportation Modifiers section, pg. 8) Comment/Recommendation: The concern on this would be that as the ambulance industry evolves and newer alternative destinations are considered covered for payment, this provision would preclude any sort of payment for transports to alternative destinations. For instance, there are multiple examples of this type of change currently occurring in the ambulance industry. On the Medicare level, a pilot program known as the ET3 model allows Medicare to pay participants for transports to alternative destinations, such as primary care offices, urgent care clinics, community mental health centers, etc. In addition, alternative destination transports have been allowed by CMS during the current COVID-19 public health emergency.

		Our recommendation would be to delete the provision which states "emergency ambulance claims, that are not treatment-in-place, are only payable with a destination modifier of H, I, or X. Valid treatment-in-place ambulance claim modifiers are identified in the Treatment-in-Place section." This provision does not allow for flexibility and innovation in the realm of ambulance transports. Providers are currently collaborating with multiple payers (Medicare, commercial insurance, etc.) on the practice of reimbursement for transportation to alternative destinations, and the Medicaid program should not have such a rigid restriction contained in the MCO manual. In addition, this language could discourage MCOs from discussing the idea of alternative destinations with providers or implementing an alternative destination program for Medicaid beneficiaries. 6. Medicaid Non-Covered Ambulance Modifiers Provision: "The MCO shall have edits in place to deny ambulance claims as non-covered services when any of the following modifiers are billed on the claim, in the any modifier field." (Medicaid Non-Covered Ambulance Modifiers, pg. 9) The modifiers listed are as follows: GY - An item or service is that statutorily excluded QL - The patient is pronounced dead after the ambulance is called but before transport. TQ - Basic life support by a volunteer ambulance provider. Comment/Recommendation: The comment on this provision is regarding the QL modifier

		being included on this list of edits which must be denied by MCOs. Medicare will pay for a "QL" response, and Medicaid is responsible for the Medicare co-pay/deductible amount up to the Medicaid allowed amount. Medicare will pay for the base rate, but not mileage when this modifier is used. If there is an automatic edit on secondary claims to deny this modifier, then Medicaid will not pay their cost sharing portion. Thus, an automatic denial edit when the QL modifier is used would lead to Medicaid not paying amounts which are owed to ambulance providers. It is our recommendation that the QL modifier be removed from this list of non-covered modifiers so that providers can be paid amounts owed when a Medicare claim crosses over to the Medicaid program.
10/27/2021 16:52	2021-LDH-10 Medical Transportation: NEMT	The Louisiana Ambulance Alliance ("the Alliance") appreciates the opportunity to comment on the recent proposed changes to the MCO manual affecting non-emergency ambulance transportation ("NEAT") in Louisiana. The Alliance is the membership organization for EMS providers in Louisiana. From Acadian Ambulance, the state's largest EMS provider, to Caddo Fire District #6, one of the state's smallest providers, we speak with one voice. For the reasons detailed below, we urge the Louisiana Department of Health adopt the following suggestions and revise the proposed MCO manual provisions posted on September 14, 2021. Provisions: The first paragraph in the Non-Emergency Medical Transportation section states "Non-emergency ambulance transportation (NEAT) is a form of NEMT that is provided by ground or air ambulance when the enrollee's condition is such that use of any other method of transportation is contraindicated or would make the enrollee susceptible to injury. NEMT and NEAT do not include transportation provided on an emergency basis…." (Non-

		Emergency Medical Transportation Section, pg. 1 of the proposed MCO Manual) Another new manual provision states "Transportation requirements in this section apply to both NEMT and NEAT services unless otherwise specified (i.e. NEMT specific guidance applies only to non-ambulance transportation)." (Non-Emergency Medical Transportation Section, pg. 1 of the proposed MCO Manual) Comments/Recommendations: These statements are ambiguous and leave a lot open to interpretation. Does this mean that there must be a specific reference to NEAT for a provision to apply to non-emergency ambulance transportation? For example, in the MCO manual, there are several sections which are general and there is no specific NEMT or NEAT reference, would these provisions pertain to NEAT? Specific examples of this include but are not limited to sections relating to Exclusions, Gas Reimbursement, Attendants, Children, Signage, Vehicle Inspections, Record Keeping etc. An illustrative example of problems due to the fact NEMT and ambulance provisions are included in the same sections appear in the Exclusions section. The text states that the MCO shall not be reimbursed for transportation to or from certain locations such as nursing homes. However, the first page clearly states that the MCO is responsible for non-emergency ambulance transportation for nursing home residents. This type of contradiction could lead to ambulance providers not being reimbursed for covered services such as transports of Medicaid enrollees to or from nursing homes. In addition, there are several sections which pertain to NEMT providers. Since NEAT is a form of NEMT under the proposed manual, would these provisions pertain to NEAT? An argument can be made that any reference to NEMT providers could include ambulance providers under the proposed revisions.

		There are fundamental differences between the NEMT program and its providers and the NEAT program and its providers. They are completely different provider types who must adhere to entirely different standards, rules, and laws. In Louisiana law, the two different types of providers are not included in any single section of law. To place them in the same grouping would be an injustice to each unique program. There should be an unambiguous delineation between NEMT and NEAT. As in the past, each different type of provider should have their own specific set of provisions in different sections of the manual. They should not be comingled and lumped into the same sections. If NEAT and NEMT provisions are included in the same sections, this will likely lead to confusion and unintended consequences for the providers, the Medicaid program including its enrollees, and MCOs. There should not be an instance in which provisions apply to both providers in one section of the manual when providers have specific sections that apply to them. All policies pertaining to NEMT should be placed in the NEMT sections of the manual and all of the policies pertaining to NEAT should be placed in the ambulance sections of the manual. They should not be comingled. The recommendation would be that any reference to NEAT being a form of NEMT be deleted. In addition, the provision that states "transportation requirements in this section apply to both NEMT and NEAT services" should be deleted. Furthermore, it is recommended that all of the provisions which pertain to NEMT be placed in the NEMT sections of the manual, and all NEAT provisions should be included in the ambulance sections of the manual. This change would ensure that there is not confusion about which rules apply to which program. Provision: The third paragraph states "See the Ambulance section of this Manual for

		additional guidelines specific to NEAT. Services shall be provided in accordance with the Louisiana Administrative Code, Title 50, Part XXVII, Chapter 5." (Non-Emergency Medical Transportation Section, pg. 2 of the proposed MCO Manual) Comments/Recommendations: The word additional is added to this section which means that there are provisions in the NEMT section which apply to NEAT. Historically, the NEMT and ambulance provisions have been clearly separated from one another. This goes back to the points made in previous comments that the provisions pertaining to NEMT and ambulance should be separated and not comingled to avoid confusion and unintended consequences since they are distinct and separate provider types. The recommendation is to delete the revision which adds "additional" to this provision. To go further into the separation of the provider types, the statement should be revised to state "See the Ambulance Section for NEAT guidelines." As stated previously, each program should have distinct sections and provisions which are separated from one another. This change would ensure that there is not confusion about which policies apply to which program. Provision: A revision to the MCO manual states, "the MCO shall ensure that transportation providers comply with the following provider responsibilities for all NEMT and NEAT services within this section." (Non-Emergency Medical Transportation – Provider Responsibilities, pg. 12 of the proposed MCO Manual) Comments/Recommendations: This seems to add ambulance providers into sections of the manual which are historically and currently NEMT provider sections. Ambulance providers have never had these requirements placed on them by statute, rule, or policy. It seems as though some of the new requirements placed on ambulance providers by this section would mandate providers be in line with requirements set out in RS 46:450.2 which applies to vehicles engaged in providing nonemergency, nonambulance transportation.

		Another example of these provider responsibilities only needing to be placed on NEMT providers is the emergency action procedure section. The vast majority, if not all, of the NEAT providers respond to 911 emergency situations and are well equipped to handle a medical emergency if one should arise during a non-emergency ambulance transport. There should not be specific provisions in a MCO manual to dictate how to handle this type of situation. This type of thing would be covered in their ambulance service's medical protocols. As stated above, these provider responsibility provisions have always pertained to NEMT providers in previous versions of the manual, and it seems to be unnecessary to include ambulance providers into this section of the manual. These provisions seem to be trying to place ambulance providers who provide non-emergency medical ambulance transportation services into the same space as traditional non-emergency medical nonambulance transportation providers when the duties, responsibilities, and requirements of the two different service providers are exceedingly dissimilar. Ambulance providers who already must meet all federal, state, and local requirements should not have additional responsibilities placed on them. The provider manual currently expresses the necessary standards and responsibilities for ambulance providers by stating: "To participate in the Medicaid program, ambulance providers must meet the requirements of La. R.S. 40:1135.3. Licensing by the Louisiana Department of Health (LDH) Bureau of Emergency Medical Services is also required. Services must be provided in accordance with state law and regulations governing the administration of these services. Additionally, licensure is required for the medical technicians and other ambulance personnel by the LDH Bureau of Emergency Medical Services." This or a substantially similar standard has historically been mandated on ambulance providers. The recommendation is that these be the only necessary requirements/standards/responsibilities placed on ambulance providers in this manual, and

		that the provider responsibilities listed in the NEMT sections of the MCO manual only apply to NEMT providers as has historically been done. The manual provision relating to provider responsibilities should state that "the MCO shall ensure that nonemergency, nonambulance medical transportation providers comply with the following provider responsibilities for all NEMT services within this section." This also goes back to previous comments that ambulance (NEAT) and NEMT provisions should be contained in separate sections of the manual for clarity and to avoid confusion and unintended consequences. It cannot be stressed enough that ambulance providers should have their own distinct and separate sections/provisions in the manual and ambulance policies/guidelines should not be added into NEMT sections. Provision: "The MCO shall ensure that the transportation provider agrees to cover the entire parish for which he or she provides NEMT or NEAT services." (Provider Requirements, General Requirements, pg. 6 of the proposed MCO Manual) Comments/Recommendations: This is another provision which has pertained only to NEMT providers throughout previous versions of the MCO Medical Transportation Manual. This provision will lead to problems in the general structure of ambulance providers. Ambulance providers are strictly governed by local governing bodies (municipalities and parishes). Providers must receive permits and permission to provide services in an area. An issue will materialize due to the fact some providers may have a permit/permission to provide services to/in a municipality within a parish, but not to/in the entire parish itself. With exclusivity agreements, it is not uncommon for a provider to have part of parish where it can provide services while another provider can provide services in the rest of the parish. This provision could possibly disqualify all providers who can currently provide non-emergency services due to the fact they can provide services within a municipality or section of the parish, but not the entire parish. This provision could leave places throughout the state without ambulance

		providers to provide non-emergency transports to Medicaid enrollees in the area. For the reasons expressed above, the recommendation would be to delete "or NEAT" services from this provision of the MCO manual. This also goes back to previous comments that ambulance (NEAT) and NEMT provisions should be contained in separate sections of the manual for clarity and to avoid confusion and unintended consequences. Historically, this provision has been contained in the NEMT section of the MCO manual. Discharges Provisions: New provisions under the Scheduling and Dispatching/Authorization Section (Scheduling and Dispatching – General Requirements, pg. 4-5 of the proposed MCO Manual) state: "Transportation providers shall pick up enrollees no later than three hours after notification by a medical facility of a scheduled discharge or two hours after the scheduled discharge time, whichever is later. Examples are as follows: ?If a medical facility notifies the MCO at 12:00 pm for a 12:30 pm discharge, the enrollee

		shall be picked up no later than 3 pm. ?If a medical facility notifies the MCO at 12:00 pm for a 2 pm discharge, the enrollee shall be picked up no later than 4 pm. ?If a medical facility notifies the MCO at 8 pm for a 7 am discharge the next day, the enrollee shall be picked up no later than 9 am." Comments/Recommendations: First of all, would this requirement apply for all NEMT and NEAT providers? It is not clear considering the wording of the manual. We completely agree that discharges from hospitals should be made timely. However, there are many scenarios in which an ambulance provider may need more than two- or three-hours advance notice to transport a patient for a hospital discharge, such as during emergency circumstances. There should be a provision where extenuating circumstances or force majeure permit a provider to transport a hospital discharge outside of these rigid parameters without consequence to the provider or the MCO. If there is an emergency or unavoidable situation, such as multiple trauma calls, a medical surge event such as a public health emergency, or a weather event, an exception should be made to these strict timelines. Adhering to these timelines for 100% of discharges will be exceedingly difficult considering the dire workforce shortage and extended hospital wait times providers are currently facing. An important note to remember is that ambulance providers are responding to unscheduled emergency calls throughout the state while also providing non-emergency ambulance services. The recommendation would be for there to be an exemption to these timelines in the manual for extenuating circumstances/good cause or force majeure.

LDH Managed Care Policies Procedures Public Comments

9/14/2020 10:09	2020-PHARM-67 Oxbryta	After reviewing the proposed changes as it relates to Oxbryta, I have some concerns that it may create barriers to therapy for some patients. Oxbryta is a Hemoglobin S polymerization inhibitor that is indicated to help increase hemoglobin in sickle cell patients ages 12 and older. It was found to increase hemoglobin on average by 1 g/dl. This is of significant importance for individuals who suffer from chronic anemia resulting in chronic complications such as sickle cell retinopathy, avascular necrosis, leg ulcers, pulmonary hypertension, proteinuria, stroke, and iron overload from multiple blood transfusions. Many of our patients that have these chronic complications may or may not experience frequent sickle cell pain crises and as a result may or may not require Hydroxyurea. Hydroxyurea is indicated to help increase fetal hemoglobin and decrease the frequency of vaso-occlusive crises. Although both medications are indicated for individuals with a diagnosis of Sickle Cell disease, they are not both indicated to treat the same complication. It's important to remember when making policies that sickle cell disease manifests itself differently in each patient and not all sickle cell therapies are appropriate for every patient. In my clinical experience, our patients have seen great benefit with taking Oxbryta and we want to ensure that all of our patients are able to continue therapy without barriers to care.
9/13/2020 14:33	2020-PHARM-67 Oxbryta	Global Blood Therapeutics would like to thank the board for this opportunity to provide written comment on the proposed criteria for Oxbryta (voxelotor), a first in class, oral hemoglobin S polymerization inhibitor indicated for the treatment of sickle cell disease (SCD) in adults and pediatric patients 12 years of age and older. This indication is approved under accelerated approval based on increase in hemoglobin (Hb). Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). The root cause of SCD is polymerization of Hemoglobin S, which leads to sickling of red blood cells and causes red blood cell destruction (hemolysis), anemia and occlusion of blood vessels. All SCD patients have anemia and decades of published studies demonstrate a significant association between anemia and end organ complications such as stroke, mortality, kidney disease, and pulmonary vasculopathy.1

		Oxbryta is the first approved treatment that directly inhibits the polymerization of Hemoglobin S. This results in reduced red blood cell sickling which increases hemoglobin and reduces hemolysis thereby improving anemia, which is a fundamental presentation of sickle cell disease. This is different from other therapies that have focused on treating or reducing symptoms such as pain crises/vaso-occlusive crisis (VOCs). Patients with SCD have very few treatment options for this devastating disease. Oxbryta offers: • Novel mechanism of action directly inhibiting HbS Polymerization • Once daily oral tablet • Rapid onset of efficacy showing hemoglobin increases in as early as 2 weeks • No extensive monitoring or titration required • Data to date has shown it is well tolerated • Use as monotherapy or in combination with hydroxyurea Global Blood Therapeutics supports the safe and appropriate use of Oxbryta tablets. _____ Would the committee consider removing the 4th bullet under the approval criteria? (requirement of members to have had two or more pain crisis in past 12 months)

		1) The primary endpoint of the Phase 3 Hope Trial, which was the pivotal trial from which Oxbryta received FDA approval, was the % of patients who achieved a > 1 g/dL increase from baseline in hemoglobin levels at week 24 a. To reiterate, Oxbryta' s novel mechanism of action addresses hemolytic anemia which is different from other therapies focused on pain crisis 2) Our study was not enriched nor powered to detect reductions in pain crises a. 42% of the patients in our Phase 3 HOPE Trial only had 1 painful crisis (VOC) in the past 12 months before enrollment 3) Our label does not include a requirement for a patient to have had previous pain crises to use Oxbryta a. Patients who suffer from anemia and hemolysis can potentially benefit from Oxbryta regardless of baseline pain crises 4) While pain crises is a complication of SCD, not all patients with SCD experience pain crisis a. In the 2019 Shah et al study, 52.3% (4456/8521) of SCD patients that were being followed had 0 VOCs during the first year of follow up and only 14.7% had one VOC during that first year of follow up.2 Requiring 2 VOCs can significantly limit access to the population of patients that could benefit from this drug. We would like to respectfully ask that you remove the proposed pain crises requirement as this is not required for patients to use or potentially benefit from Oxbryta or modify it to reflect the inclusion criteria and pain crisis definition used within our study as proposed below.

		The SCD population is heterogeneous and the pain crises experienced by patient can vary in presentation and treatment requirements. The standard of care for the management of pain crises are typically opioid analgesics, NSAIDs or other pain medications. Access to a healthcare facility can also be limited based on where the patient lives as well as other factors. As such, if you deem it necessary to include prior VOCs as an eligibility criterion, we ask that the definition of a VOC reflects the definition used in the Phase 3 HOPE Trial. 1) Our trial included patients with 1 to 10 VOCs within 12 months prior to enrollment. 2) VOCs/Painful crisis in our Phase 3 HOPE trial was defined as acute painful crisis or acute chest syndrome for which there was no explanation other than VOC that required prescription or healthcare professional instructed use of analgesics for moderate to severe pain. There was no requirement for: a. Parental ONLY pain medication (patient could take oral medication) b. A visit to an emergency room or medical facility (patient could call their doctor or follow guidance of home pain medication treatment) c. Did not require occurrence of priapism or splenic sequestrations Thank you for your consideration. 1. Ataga KI, Gordeuk VR, Agodoa I, et al. Low Hemoglobin Increases Risk For Cerebrovascular Disease, Kidney Disease, Pulmonary Vasculopathy, and Mortality in Sickle Cell Disease: A Systemic Literature Review and Meta-Analysis. PLoS ONE 2020;15(4): e0229959.

		2 Shah N, Bhor M, Xie L, et al. Sickle Cell Disease Complications: Prevalence and Resource Utilization. PLoS ONE 2019;14(7):1-12.
8/12/2020 14:05	2020-PHARM-67 Oxbryta	• I have been a sickle cell provider (and Louisiana State Sickle Cell Committee Member) for more than 15 years. The criteria noted in your proposed managed care policy for Oxbryta should be re-evaluated. My recommendations are noted below. Additionally, I would respectfully like to request an opportunity to appear in person to provide education regarding sickle cell disease. First, the life expectancy of patients with sickle cell disease in the United States remains < 45 years of age. This is NOT exclusively or primarily related to severe vaso-occlusive events, but is directly related to end organ damage that is a direct result of chronic hemolysis, iron overload and infarction events that are often silent. With this in mind please review my comments noted with your recommendations below: The recipient is 12 years of age or older on the date of the request; AND • The recipient has a diagnosis of sickle cell disease; AND • If possible, voxelotor (Oxbryta®) is prescribed by, or the request states that this medication is being prescribed in consultation with, a hematologist or oncologist; I agree with this completely. Patients with sickle cell disease should be seen by an experienced hematologist/sickle cell provider annually. This would facilitate both appropriate prescribing AND management. It should NOT read if possible, it should read "must."

		AND • The request lists dates of TWO or more sickle cell-related pain crises within the previous 12 months, where painful crisis is defined by EITHER: o a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered narcotic or parenterally administered ketorolac; OR o the occurrence of chest syndrome, priapism, or splenic sequestration; AND The should NOT be listed as a requirement, but should be listed as "OR" with: Chronic Hemolytic Anemia (below normal hemoglobin, elevated LDH and elevated bilirubin) OR Serum Ferritin >1000, positive Ferri-scan, or liver biopsy - consistent with iron overload OR MRI/CT or Bone Scan with evidence of silent infarction, bony necrosis, AVN or Moya Moya of the CNS OR Abnormalities of Urinary Microablumin that requires intervention per the NHLBI Sickle Cell Guidelines OR

		Sickle Cell Related Retinopathy OR History of thrombosis/DVT/PE With the limits currently written, there is an implication that VOC is the only cause of death, when it only a symptom in some patients with sickle cell disease. It also implies that the other major contributors to the severely reduced life expectancy of patients with sickle cell disease are non-existent. Finally, and this is the worst implication, it seems to connect this policy to cost related measures and NOT to the facts of sickle cell disease. • ONE of the following is stated on the request: o The recipient is currently receiving hydroxyurea therapy; OR o The recipient has a history of treatment failure, intolerance, or contraindication to hydroxyurea therapy; The above written statement should also include: OR Patients that have refused Hydroxyurea due to family planning and concerns with the

		possible teratogenic effects associated with Hydroxyurea. **Patients should not be forced to use a therapeutic agent like Hydroxyurea if they are of childbearing age or a female patient and have concerns with the teratogenic effects associated with this therapy. To deny a patient the opportunity to use Oxbryta under this circumstance seems unethical, and I would suggest that this be re-evaluated.** AND • By submitting the authorization request, the prescriber attests to the following: o The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; AND o All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; AND o The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

		I agree with the above Black Box statement completely. Respectfully Submitted, Tammuella Chrisentery Singleton, MD Director of Pediatric Hematology Director, Hemophilia Treatment Center Louisiana Center for Advanced Medicine
8/11/2020 12:01	2020-PHARM-67 Oxbryta	I am writing to you regarding the drug, Oxbryta, which is manufactured by Global Blood Therapeutics. This drug has, as an indication, improvement in hemoglobin and in parameters associated with hemolysis. The trial of Oxbryta was not sufficiently powered to allow an analysis of its effect on vaso-occlusive crisis. However, its ability to improve the hemoglobin of individuals with sickle cell disease is impressive and individuals with sickle cell disease who have been placed on the drug have remarked that they have more energy, feel so much better. One patient informed me that the drug had been "a game changer." Many times, the problems associated with chronic anemia have been down-played. Yet, chronic anemia and hemolysis are associated with chronic fatigue, cognitive difficulties, the development of stroke, cardiomegaly, development of pulmonary hypertension and so much more. The effect of the drug is independent of the effects of hydroxyurea. It must be remembered that there are numerous reasons why an individual may not be able to be on hydroxyurea. These include hypersensitivity to the drug, inability to tolerate the medication due to neutropenia, megaloblastic anemia, nausea, concerns about its possible carcinogenic potential, potential teratogenic effect, or its leading to hypospermia. Oxbryta has the potential to allow individuals to live a more normal life. I would hope that those who have a primary professional caregiver such as an NP or general practitioner might be able to avail

		themselves of this medication and others that might come through the pipeline. Also, alleviation of anemia by itself should be a commendable goal. There should not be tacked onto the requirements for prescribing the drug a proviso that crisis had to have been present. We would hope that Medicaid insurers of those with sickle cell disease would be sensitive to the needs of those who are their clients and provide them with the medication(s) that can enhance their lives.
2/28/2020 20:51	2020-ABA-1 ABA Required Documenation per Codes	I've reviewed the documentation guidelines outlined. I appreciate having a standard outlined clearly. However I have some concerns: 1. The dating references Jan 1 2019. It's inappropriate to backdate guidelines/standards now. It should be dated forward for once guidelines are outlined and shared with all providers. 2. Data sheets should be a part of the accepted documentation. They need to be accompanied by notes but not excluded. Data sheets have the most information about what occurred and are the primary source for a session. 3. Some of the language in what should be included in the daily note is concerning. For an RLT to document each intervention used that day. Multiple are used a day and simultaneously. Thank you
2/28/2020 20:49	2020-ABA-4 Applied Behavior Analysis Fee Schedule Coding Update	The rates for the fee schedule are not adequate. Medicaid has decreased the rate over the years, making it harder to get more providers, as well as to get and retain quality providers, and whereas it didn't decrease this year, it also is still below what is necessary for providing quality services. On top of decreasing rates, medicaid continues to increase the demands. Increasing demands and stress without compensation of the increased workload leads to burnout and reduction in services. Also, BCBA's should be paid a higher rate for providing therapy to clients than someone

		with no ABA experience/degree at a bachelors level. Same for BCaBA's; please bring back rate options for higher level therapy services. Also, the three original codes were a lot more self-explanatory and easier, so less room for error. Please consider going back to a smaller, easier list, as well as an increased rate. Please also consider allowing group parent training with client codes. This is a HUGE way to help with generalization of skills, as well as aid in transition of services. Group rates are also too low. I love that there are now group options for services, and that you now reimburse for multiple therapists. Please consider doing the rate for per therapist with a cap, as sometimes the severely aggressive clients take three therapists and a supervisor, and older aggressive clients may take even more, especially in community based services, to ensure safety. Thank you for recognizing this need and making this available for our clients, as providing services to clients with more destructive behaviors requires more resources and isn't sustainable without the added compensation for those resources. We appreciate you giving us the opportunity to provide feedback, and your consideration in all of this.
2/28/2020 18:34	2020-ABA-1 ABA Required Documenation per Codes	My first concern is that this states that these requirements are for "dates of service on or after Jan. 1, 2019), but aren't expected to have final posted expectations until August 2020. We should not be held liable for documentation requirements before they have been finalized and posted for all providers. For code 97151 requirements: Assessments and data collection should be able to be used for documentation of providing the service. Also, the maximum time allowed for 97151 should be adjusted due to the large amount of requirements to complete the service. Other companies allow 6 hours, and it really takes longer than that to complete, especially for an initial plan. The updates in the treatment plan with descriptions, along with the analyzed

		data, graphs, and the formal assessments should count as documentation. A separate session note should not be required. 97153/0373T/97154: progress made/not made (other than the data collected) and future plans are not tech duties; this should not be part of a therapist session note, but of supervision documentation. Also, data collection should be accepted as documentation of providing the service, as well as meeting these requirements. Also, parent involvement belongs in parent training notes, not therapy session notes. 97155: Data collection should be accepted as documentation of services. 20% of supervision allowed is great, but is a lot to be required; ethical requirements by the national board is 5%. 97156/97157/97158: Data collection should be accepted as documentation of services. for 97158, 20% required is a lot, but great to have that as an option.
2/28/2020 16:11	2020-ABA-4 Applied Behavior Analysis Fee Schedule Coding Update	In reference to my previous posting there were 2 typographical error's. These sentences should read as follows: Any additional notes should only serve to clarify the data and should NOT be used to supplant the data Again, narrative or anecdotal information DO NOT represent a true way to illustrating progress.
2/28/2020 15:14	2020-ABA-1 ABA Required Documenation per Codes	DATA COLLECTION: In general the statement "data collection is insufficient for medical records" may infer that data should not be part of a medical record. The data are the only objective component to the record. Behavior Analysts have to rely to data to make decisions. It might be better to state the collection of raw data alone is not sufficient for a complete medical record. It is likely important for data (raw and graphical) to make up a substantial part of the record otherwise the information provided may be highly subjective and less than accurate. Saying something occurred is not the same a having evidence of what did or did not occur. Any additional notes should only serve to clarify the data and should be used to

		supplant the data. I believe strongly this would fly in face of generally accepted behavior analytic procedures. What is being inferred is that the narrative or anecdotal information is valued more than the actual data generated within the session. I argue that this might lead to LBAs minimizing the importance good data and that will likely lead to ABA services provide with much less fidelity. 97153 Code: It was requested that the documentation include a specific intervention. I doubt only one ABA intervention would be involved. Considering the potential source of the problem there are likely several. Is this information required by other types of providers? The response to the intervention is found in the data and not in narrative or anecdotal notes. The progress made is determine by the graph. Hence the important of the data. Again, narrative or anecdotal information represent a true way to illustrating progress. The rest of the information requested with this may not be in a scope of competence of the RLT (who provides the service with this code). For example, determining "future plans" (I'm assuming this is referring to future treatment plans) is related to an analysis conducted by the supervisor (LBA). Additionally, documentation of parent involved/family changes for this code is not necessarily applicable because in most cases the parent is not involved in the delivery of the code's service provision and family changes may not be information accessible to the RLT. The compliance with the target and the response are again found in the actual data generated within the session. Other codes: It should be noted that the above information is very similar to what is requested for the remaining codes. I have similar concerns because the information is not necessarily germane to the service provided within the code description and doesn't add anything meaningful regarding documentation that could not be obtained from raw and graphical data with appropriate clarifying information.

LDH Managed Care Policies Procedures Public Comments

2/28/2020 15:00	2020-ABA-1 ABA Required Documenation per Codes	Comments are broken down based on each item that was included in the documentation guidelines per code with comments for each one. I only commented on the codes that I use most often in my practice. 97153 • requirements in the ABA Medicaid Manual (Data collection is insufficient for a medical record.) – I think that it is great to be working on documentation guidelines for ABA providers! It would be great if we could have some discussion about the pieces that make data collection insufficient for the medical records and use that as a base for the documentation guidelines. I do agree that there are somethings that are not going to show in the data and those things should be included in the sessions note. Looking at the reasons why data alone is insufficient would serve as a good guide of what should be included in the note. • what specific ABA intervention used -The definition of code 97351 is, " behavior treatment by protocol." The protocol is developed by the supervising LBA and includes the specific procedures that are to be used. The protocol specifies the specific antecedent and consequences that should be used for each teaching trial. These are decisions that are made LBA prior to the 97153 service being provided. Evidence should be provided that the individual implementing 97351 was following the protocol that was created by the LBA. The data collected during the service is one piece of evidence that can be provided. The session note that should include some of the items that the student did well with and had trouble with which is further evidence. The session note is a brief summary. It does not include all of the interventions used, behaviors that occurred, or teaching that took place. This information is all found in the protocol that is being implemented as well as in the data. • what was the response to the intervention – ABA is a research-based field that relies on objective data when determining the effectiveness of a treatment. It would not be appropriate for an unlicensed individual to make an assumption on the response to intervention based on their experience. The supervising LBA analyzes data in order to make decisions on if the intervention was effective and makes changes to the protocol when appropriate.

		• any notes risks/problem areas – It is appropriate to include challenges that were faced during the session in the session note. There are times that there may be a lower data count due to lack of motivation, new behaviors that occurred, or high rates of stereotypical behavior. These "problems" should be noted in the session not and provide justification for the lower number of data points that were collected during the service. It is not appropriate to include "problem areas" in regards to skill deficits. Skill deficits are measured using objective assessments and are not a part of this service. • significant problem not associated with objective, - I am unsure of what this means. Is it a typo? The previous bullet point should cover any "problem areas." Maybe I misinterpreted the previous point and my response for that one should go here. Consider rewording this and the previous bullet point for clarity. • future plans – "treatment by protocol" is the definition for this code. When implementing this service, the individual is following the protocol. The LBA, with parent input, is the only one qualified to make decisions regarding the "future plans" of the items on the protocol. It is not appropriate for someone implementing this code to make comments regarding "future plans." • documentation of parent involvement – this code coves LBAs, SCABAs, and RLTs. It does not cover parents. Therefore, it would be odd to document parent involvement. Parent training is covered by a different code and parent involvement should be well documented. • family changes. – family changes would not affect the implementation of the protocol and are therefore inappropriate to include in a session note. Additionally, changes in the family is information that should be shared with the supervising LBA and most often is not shared with the RLT and other staff members due to confidentiality. • Etc – this leaves things unclear. The session note should include information that pertains to implementing the adaptive protocol. 97154 – see comments regarding 97153. They apply to this code as well. 97151

		• Session Notes – is this just restating that there should be a session note? • primary target – unsure what this means. Does it mean administering the assessment versus analyzing data? • treatment plan matches the notes – the assessment is used to create the treatment plan. If an initial assessment is being conducted then there is no treatment plan yet. Does this mean that the results of the assessment are used when creating treatment plan? • list of objectives describe barriers and/or what tools will be used to meet barriers – does this refer to problematic behaviors? Some assessments include barriers assessments and others do not. Additionally, the symptoms that the student has related to their diagnoses are the barriers to learning. I am unsure what needs to be recorded in order to fulfill this item. • Content of the session to include what activity and measures were administered during the assessment. – the data from the assessment will show exactly what activity and measures were administered. The results/data from the assessment should be sufficient for this item. 97152 – see comments regarding 97151
2/28/2020 14:46	2020-ABA-1 ABA Required Documenation per Codes	Requirements for 97153 are redundant and in many cases unnecessary. I would not feel comfortable with an RLT being responsible for completing many items required without immediate oversight. In many cases this would be a violation of confidentiality. Majority of required information is provided in treatment requests and not in line with session documentation for many other mental health professionals. As written, the supervision requirements for 97155 would far exceed the requirements outlined in the Louisiana Behavior Analyst Practice Law.
2/28/2020 9:55	2020-ABA-1 ABA Required	The proposed session note requirements for the 97153 codes, do not reflect that of the expertise level of an RBT. Identifying future plans or the effects of setting events on learning

	Documenation per Codes	are rolls of the BCBA. Data collected, as well as programming documentation reflects many of these areas including current goal, interventions in place, and progress towards achieving the goal. Additional observational notes will be repetitive and require time taken away from direct services with the client. The proposed session note requirements for 97158 code, reflects having families/caregivers grouped together rather than clients.
2/27/2020 21:02	2020-ABA-1 ABA Required Documenation per Codes	The documentation requirement for session notes for CPT code 97153 seem excessive for a 15 minute session.
2/27/2020 17:09	2020-ABA-1 ABA Required Documenation per Codes	Good afternoon, I feel it is my responsibility to comment upon the policy listed above (2020-ABA-1) and the grave concerns I have with the specific notion that states "data collection is insufficient for a medical record." Based on the focus on objectivity and data driven decisions within our field along with the years of research to support the use of data driven decision making and in turn the results of such efforts, not using data collections as a form of notion of one's progress is extremely concerning. I am writing to state my concerns with data not being a sufficient means to record medical services. It would be greatly appreciated if consideration was made to establish that data collections and or visual representations of such data (i.e., graphs) were written into the alignment of policy 2020-ABA-1 regarding the required documentation per codes. Thank you, Tricia Clement, Phd, LBA, BCBA-D
2/27/2020 13:05	2020-ABA-1 ABA Required Documenation per Codes	I am writing on behalf of the Louisiana Coalition for Access to Autism Services (LCAAS). LCAAS is a coalition of ABA therapy providers with a mission of expanding access to high-quality autism services throughout Louisiana. We have a concern that some of the documentation requirements contained in the proposed rules are not only overly burdensome, but also require certain professionals to provide information not within their scope. The requirements for code 97153, for example, pertain to services provided directly by a registered behavior technician (RBT or "line tech"). Line techs have a significantly lower level of training and education than licensed behavior analysts who provide the supervision. Line techs also may not have access to information such as future plans and the full scope of

		parent involvement in the treatment plan, which are requirements included in the proposed rules. The proposed documentation requirements will thus be burdensome to line techs on multiple fronts based on their scope and the length of time required. Additionally, much of the information requested (barrier, parent involvement response to intervention) are reported in the 6th month treatment review, which we believe is sufficient. Separately, the language "It is not required that a separate session note be created for every 15 minute unit; just ensure that all units billed are accounted for" is vague. It does not provide BCBAs or line techs with certainty over what documentation is required. LCAAS is happy to meet with LDH officials to discuss the documentation requirements in detail.
2/27/2020 11:11	2020-ABA-1 ABA Required Documenation per Codes	I have concern with the recommended documentation for the 97153 and 97154 codes specifically. As these codes (97153 in particular) are used daily, I don't believe the recommended documentation provided on a daily basis is going to yield any additional insight as to whether or not the service was completed any more than providing a data sheet, graph, objective, sign in/out or other already kept documentation would do. Further, a line technician, who may be the only person seeing the client on a specified day may provide anecdotal observations but is by no means necessarily qualified to outline the commentary that is being recommended. I also have concern with the percentage requirement for documentation of the 97155 code. 2 hours per 10 hours of therapy or 1 hour per 5 hours of therapy is not based on medical necessity. This amount of supervision does not match any recommended guidelines for ABA supervision, it does not lend to appropriate reduction of services/hours/support, or any other evidence based requirement for supervision. The content of the supervision documentation is fine, just the hours requirement is the issue.
2/26/2020 20:17	2020-ABA-2 ABA Audit Tool Overview	There are two places in the ABA Provider Audit Tool draft where requirements are not consistent with the MCO requirements/manuals as applies to documentation of professional/behavioral health services. We are requesting that LDH edit these two items to align with the MCO provider manuals and thus create consistent documentation standards, especially for those of us who are providing more than just ABA. As currently written, the

		LDH draft places an undue burden on providers to reprogram their electronic medical records for ABA only documentation. Location 1: Page 2, item number 4. It reads: "4. The responsible service provider's name, professional degree and relevant identification number." What we are currently required to do is provide a signature of full name followed by degree and credentials for rendering providers. Our understanding of this requirement as it should translate to the ABA Audit tool is: John Doe, MS, LBA, BCBA or Sarah Brown, BA, BCaBA, or Todd Smith, BA, or Sam Smith (no degree follows). We are not currently putting license numbers or MCO provider identification numbers (of which there are different numbers for each MCO) inside a professional signature and are requesting this never be required. We are requesting that LDH use the MCO provider manuals language here and change "relevant identification number" to "relevant credentials." Page 4, General Member Information, item 1. This currently reads: "1. Member name and MCO ID# on every page." Again, this is not reflecting the language and requirements in the current MCO provider manuals. The MCOs use the term "unique practice identifier" or "unique practice ID." For those of us using electronic medical records that also conform to traditional allied and behavioral health services, those medical records systems assign a patient a unique identifier, usually alpha and numeric, that allows unified record keeping. So if a child gets a name change due to adoption, we can run a continuous record. If the child changes MCOs, we can run a continuous record. We do not track children by MCO ID# because children may change MCOs, thus breaking the continuity of the record. Our electronic record automatically prints the unique practice identifier on each page of the record. This is also a way to identify a child without using too much protected health information. Thus, we are requesting that LDH replace the language "MCO ID# on every page" with "unique practice ID." We would like to thank LDH for the time and effort in drafting this document. It will be helpful to have going forward. We also wish to thank LDH for otherwise (these two places as an exception) being very conscious of aligning the ABA audit requirements with the standing LDH behavioral health provider audit requirements. The continuity helps with efficiency and effectiveness.

LDH Managed Care Policies Procedures Public Comments

2/26/2020 19:54	2020-ABA-1 ABA Required Documenation per Codes	Code 97151 does not require an encounter note with the depth of information in the required documentation column in this draft because the plan document itself is the product of time spent in this code. The plan document stands alone and contains the prescribed elements in the encounter note description. As written, LDH would be asking providers to double document, which is inconsistent with other realms of behavioral health services provision. Instead, the required documentation should read: "Completed ABA Treatment Plan per guidelines in the LDH ABA manual. Documentation either within the treatment plan or in a session note that specifies date(s) of service and time(s) and signed per the LDH ABA manual guidelines. " 97153 LDH should specify that a session note is the equivalent of the Daily Log. The current LDH ABA manual has outlined criteria for a Daily Log that align with the drafted documentation requirements. 97155 A separate session note should not be required if the provider is documenting the provision of supervision and items otherwise listed in the LDH draft on the Daily Log, which also documents 97153. The most critical elements of documentation for 97155 are (1) start and stop times [omitted from LDH description] and (2) real time changes in prescribed treatment documented for inclusion in the treatment plan ongoingly. 97156 A separate session note should not be required for each date of occurrence if the provider is documenting the items for 1:1 family training on the Daily Log and more thoroughly capturing the training in a weekly supervision and family training note that synthesizes the full week's progress. For example, we do short bursts of family training daily (15 minutes) to best support implementation and continuity. The process and outcome are documented in a narrative weekly note that provides a bigger picture of progress. We are capturing daily start and stop times, participants, and points of emphasis of family training in the Daily Log. Because 1:1 family training is an important daily tool for us in engaging families and making sure that they are taking home and applying the critical points of the day, we ask that LDH allow providers some flexibility in this documentation. Thank you for the opportunity to comment.
2/26/2020 13:18	2020-ABA-1 ABA Required	Please see below my questions/comments regarding the required documentation per codes.

	Documenation per Codes	97151- does the treatment plan count as a session note if all of what was conducted/observed in the assessment is included? I feel as though a session note that is separate may be highly redundant and time-consuming when our company is already struggling to conduct the assessment and write the treatment plan in the amount of time that insurance companies are authorizing (usually 4 hours). 97152/97155- For baseline that is being conducted in order to add new targets after clients have mastered everything in their 6-month treatment plan, which code is billed for? For baseline, this may not include a full assessment being conducted. 97157- Can this include general workshops hosted by the center that apply towards the clients whose family attends (i.e., general ABA content discussed that is included in the billed client's program without specific client programming) or does client-specific discussion need to happen in order for this code to be billed? My concern is related to HIPAA but still wanting to bill accurately.
2/22/2020 10:32	2020-ABA-1 ABA Required Documenation per Codes	97151/2, 0362T. Updated treatment plan should be accepted in lieu of session note for assessments, as it necessarily requires all of the proposed documentation anyway.
10/14/2019 13:19	2019-PDL-1 Advair - PDL Changes	I thought that once all of the Bayou Health Plans merged to a single uniform PDL, it was to stay t he same and not change, for the simple fact all providers and pharmacies would be on the same page and not have to go back and forth between health plans to see which ones required PA's for which medications. That apparently was not very well thought out. If one plan is going to change the criteria for it to be approved and/or denied, it should be that way for all of them. We are right back to square one having to do PA's for nearly every single medication that is prescribed for patients, whether they have Medicare, private insurance or Medicaid, which is ridiculous. The government has micromanaged everything to the point the providers cannot even practice medicine without the interference of insurances.

LDH Managed Care Policies Procedures Public Comments

9/17/2019 9:03	2019-HPA-1 Severe Combined Immunodeficiency (SCID)	The Office of Public Health, Genetics Diseases/Newborn Screening Program requests that Medicaid reference and add the LAC from Oct. 20, 2018 in the HPA regarding the addition of SCID to the Newborn Screening panel so that the MCOs know to plan for retroactive effective date back to the Rule Date drop.