Changes to Statement of Work

Item	Change From:	Change To:	Justification
1	5.4.1.2.1 Physician Incentive Plans 5.4.1.2.1.1 In accordance with §422.208 and §422.210, the MCO may operate a Physician Incentive Plan, but specific payment cannot be made directly or indirectly under a Physician Incentive Plan to a physician or physician group as an inducement to reduce or limit medically necessary services furnished to a member.	5.4.1.2.1 Physician Incentive Plans 5.4.1.2.1.1 In accordance with 42 C.F.R. §438.3(i), §422.208, and §422.210, the MCO may operate a Physician Incentive Plan, but specific payment cannot be made directly or indirectly under a Physician Incentive Plan to a physician or physician group as an inducement to reduce or limit medically necessary services furnished to a member.	
2	5.4.1.2.2. Value-Based Payments … 5.4.1.2.3.1. Annually, by August 30 of the current contract year, submit to LDH a written VBP mid-year report describing the implementation and status of its VBP use and evidence that each VBP model includes financial incentives for providers linked to at least two of the MCO incentive-based measures in Attachment C, or other Attachment C measures for non-primary care VBP arrangements. As part of its VBP agreements, the MCO shall not hold providers accountable for meeting a higher target for the incentive-based measure than the target to which LDH holds the MCO for the same measure unless the provider is already performing above the benchmark set by LDH for MCO performance on the IB measure. 5.4.1.2.3.1.1. If an MCO implements a VBP arrangement with primary care providers, the VBP arrangement must include at least two incentive-based measures in Attachment C in order for the MCO to report the primary care VBP in its Attachment E VBP reporting. 5.4.1.2.3.1.2. If an MCO implements a VBP arrangement for services other than primary care, the MCO must include at least any two applicable measures from Attachment C in the VBP arrangement, in order for the MCO to count the non-primary care VBP in its Attachment E reporting. If there are not at least two applicable measures in Attachment C, the MCO must justify its rationale for	5.4.1.2.2. Value-Based Payments … 5.4.1.2.3.1. Annually, on or before ~~by~~ August 30 ~~of the current contract year~~, submit to LDH a written VBP mid-year report describing the implementation and status of its VBP use and evidence that each VBP model includes financial incentives for providers linked to at least two of the MCO incentive-based measures in Attachment C, or other Attachment C measures for non-primary care VBP arrangements. As part of its VBP agreements, the MCO shall not hold providers accountable for meeting a higher target for the incentive-based measure than the target to which LDH holds the MCO for the same measure unless the provider is already performing above the benchmark set by LDH for MCO performance on the ~~IB~~ incentive-based measure. 5.4.1.2.3.1.1. If an MCO implements a VBP arrangement with primary care providers, the VBP arrangement must include at least two incentive-based measures in Attachment C in order for the MCO to report the primary care VBP in its Attachment E ~~VBP~~ reporting. 5.4.1.2.3.1.2. If an MCO implements a VBP arrangement for services other than primary care, the MCO must include at least any two applicable incentive-based measures from Attachment C in the VBP arrangement, in order for the MCO to count the non-primary care VBP in its Attachment E reporting. If there are not at least two applicable incentive-based measures in Attachment C, the	These revisions will allow LDH flexibilities regarding VBP withhold determinations and COVID-19 impacts. In addition, Attachment E has been revised to provide clarification to the MCOs and capture additional data that appears in the VBP Strategic Plan.

Item	Change From:	Change To:	Justification
	selecting different VBP measures and must seek approval from LDH to include the VBP arrangement in its Attachment E reporting. 5.4.1.2.3.1.3. To increase simplification and consistency in provider performance data reporting, the MCO must use performance measure specifications in its VBP arrangements that align with the LDH specifications for measures in Attachment C where the MCO is utilizing any measure included in Attachment C. … 5.4.1.2.3.1.1. If an MCO implements a VBP arrangement with primary care providers, the VBP arrangement must include at least two incentive-based measures in Attachment C in order for the MCO to report the primary care VBP in its Attachment E VBP reporting. 5.4.1.2.3.2. Annually, by March 15th submit to LDH a report on its VBP use for the prior Calendar Year as specified in Attachment E and a VBP year end report. In reporting its VBP use and provider payments, the MCO shall use a "date of payment" approach to complete Attachment E. 5.4.1.2.3.3. If LDH determines that the MCO use of recognized VBP models meets both of the following two VBP targets, LDH will refund any remaining amounts withheld for VBP. Recognized VBP arrangements exclude LAN APM category 2B (pay for reporting) models and VBP models that do not have a link to at least two of the applicable MCO performance measures in Attachment C as defined in 5.4.1.2.3.1 above. … 5.4.1.2.3.3.3. LDH will refund to the MCO half of the remaining amounts withheld for VBP during if the MCO meets either the VBP targets in 5.4.1.2.3.3.1 or 5.4.1.2.3.3.2.	MCO must justify its rationale for selecting different VBP measures and must seek approval from LDH to include the VBP arrangement in its Attachment E reporting. 5.4.1.2.3.1.3. To increase simplification and consistency in provider performance data reporting, the MCO must use performance measure specifications in its VBP arrangements that align with the LDH specifications for measures in Attachment C ~~where~~ when the MCO is utilizing any measure included in Attachment C. … 5.4.1.2.3.1.1. If an MCO implements a VBP arrangement with primary care providers, the VBP arrangement must include at least two ~~incentive-based~~ measures ~~in~~ from Attachment C, one of which must be an incentive-based measure, in order for the MCO to report the primary care VBP in its Attachment E VBP reporting. … 5.4.1.2.3.2. Annually, ~~by~~ on or before March 15th submit to LDH a report on its VBP use for the prior Calendar Year as specified in Attachment E and a VBP year end report. In reporting its VBP use and provider payments, the MCO shall use a "date of payment" approach to complete Attachment E. If the MCO did not meet the VBP targets identified in 5.4.1.2.3.3 below, the MCO shall describe why the VBP targets were not met. 5.4.1.2.3.3. If LDH determines that the MCO's use of recognized VBP models meets both of the following two VBP targets, LDH will refund any remaining amounts withheld for VBP. Recognized VBP arrangements exclude LAN APM category 2B (pay for reporting) models and VBP models that do not have a link to at least two of the applicable MCO performance measures in Attachment C as defined in 5.4.1.2.3.1 above.	

Item	Change From:	Change To:	Justification
	… [Add new section] … 5.4.1.2.4. LDH shall retain the amount of the VBP withhold not earned back from the MCO.	… 5.4.1.2.3.3.3. LDH will refund to the MCO half of the remaining amounts withheld for VBP during the calendar year if the MCO meets either the VBP targets in 5.4.1.2.3.3.1 or 5.4.1.2.3.3.2. … 5.4.1.2.3.3.5. LDH may refund to the MCO some of the remaining amounts withheld for VBP during the calendar year if the MCO partially meets one or both of the VBP targets in 5.4.1.2.3.3.1 and 5.4.1.2.3.3.2 and describes to LDH's satisfaction why the MCO did not fully meet the VBP targets. … 5.4.1.2.4. LDH shall retain the amount of the VBP withhold not earned back ~~from~~ by the MCO.	
3	5.7.1. LDH will develop cost-effective and actuarially sound rates according to all applicable CMS rules and regulations. LDH will not use a competitive bidding process to develop the MCO capitation. LDH will develop monthly capitation rates that will be offered to MCOs on a "take it or leave it" basis. 5.7.2. Rates will be set using fee-for-service claims data, Medicaid Managed Care Shared Savings claims experience, Medicaid Managed Care MCO encounter data, LBHP encounter data, and financial data and supplemental ad hoc data and analyses appropriate for determining actuarially sound rates. Fiscal periods of the base data will be determined based upon the data sources, rate periods and purposes for which the data is used with appropriate adjustments which include the following: …	5.7.1. LDH will develop cost-effective and actuarially sound rates ~~according to~~ in accordance with 42 CFR §438.4 through §438.7 and all applicable CMS rules and regulations. LDH will not use a competitive bidding process to develop the MCO capitation. LDH will develop monthly capitation rates that will be offered to MCOs on a "take it or leave it" basis. 5.7.2. Rates will be set using ~~fee-for-service claims data, Medicaid Managed Care Shared Savings claims experience, Medicaid Managed Care MCO encounter data, LBHP~~ encounter data, ~~and~~ financial data, and supplemental ad hoc data and analyses appropriate for determining actuarially sound rates. Fiscal periods of the base data will be determined based upon the data sources, rate periods and purposes for which the data is used with appropriate adjustments which include the following: …	These revisions provide flexibility to utilize the additional options related to rate development established by the managed care final rule published on November 13, 2020. Revisions also remove duplication and the use of obsolete data in rate setting.

Item	Change From:	Change To:	Justification
	5.7.4. Any adjusted rate must continue to be actuarially sound and consistent with requirements set forth in 42 CFR §438.6(c), and will require an amendment to the Contract that is mutually agreed upon by both parties. 5.7.5. Additional factors determining the rate for an individual member may include: 1) age; 2) gender; 3) Medicaid category of assistance; 4) the geographic location of the member's residence; and 5) Medicare enrollment. 5.7.6. As the MCO Program matures and FFS data and Shared Savings data are no longer available, there will be increasing reliance on encounter data and/or financial data to set future rates, subject to comparable adjustments. 5.7.7. The MCO shall be paid in accordance with the monthly capitated rates specified in Contract Attachment D – Mercer Certification, Rate Development Methodology and Rates of this Contract. 5.7.8. The rates will be reviewed and may be periodically adjusted. Any adjusted rates shall be actuarially sound and consistent with requirements set forth in 42 CFR §438.6(c). 5.7.9. The MCO shall provide in writing any information requested by LDH to assist in the determination of MCO rates. LDH will give the MCO reasonable time to respond to the request and full cooperation by the MCO is required. LDH will make the final determination as to what is considered reasonable.	5.7.4. ~~Any adjusted rate must continue to be actuarially sound and consistent with requirements set forth in 42 CFR §438.6(c), and will require an amendment to the Contract that is mutually agreed upon by both parties.~~ ~~5.7.5.~~ Additional factors determining the rate for an individual member may include: 1) age; 2) gender; 3) Medicaid category of assistance; 4) the geographic location of the member's residence; and 5) Medicare enrollment. ~~5.7.6. As the MCO Program matures and FFS data and Shared Savings data are no longer available, there will be increasing reliance on encounter data and/or financial data to set future rates, subject to comparable adjustments.~~ 5.7.5~~7~~. The MCO shall be paid in accordance with the monthly capitated rates specified in Contract Attachment D – Mercer Certification, Rate Development Methodology and Rates of this Contract. 5.7.6~~8~~. The rates will be reviewed and may be periodically adjusted. Any adjusted rates shall be actuarially sound, ~~and~~ consistent with requirements set forth in 42 CFR ~~§438.6(c)~~§438.4 through §438.7, and will require an amendment to the Contract. 5.7.7~~9~~. The MCO shall provide, in writing, any information requested by LDH to assist in the determination of MCO rates. LDH will give the MCO reasonable time to respond to the request, and full cooperation by the MCO is required. LDH will make the final determination as to what is considered reasonable.	
4	5.9.1. In accordance with the MCO Financial Reporting Guide published by LDH, the MCO shall provide an annual Medical Loss Ratio (MLR) report following the end of the MLR reporting year, which shall be a calendar year. 5.9.1.1. An MLR shall be reported in the aggregate, including all medical services covered under the contract.	5.9.1. In accordance with the MCO Financial Reporting Guide published by LDH and 42 CFR §438.8, the MCO shall provide an annual Medical Loss Ratio (MLR) report following the end of the MLR reporting year, which shall be a calendar year.	Under a provision of the SUPPORT Act, Louisiana would be entitled a larger share of any MLR rebate received from a contracted Managed Care Entity. CMS has allowed for the Federal share of MLR remittance attributable to Expansion populations to be calculated at regular Federal Medical

Item	Change From:	Change To:	Justification
	5.9.1.1.1. If the aggregate MLR (cost for health care benefits and services and specified quality expenditures) is less than eighty-five percent (85%), the MCO shall refund LDH the difference. Any unpaid balances after the refund is due shall be subject to interest at the current Federal Reserve Board lending rate or ten percent (10%) annually, whichever is higher. 5.9.1.2. LDH may request MLR reporting that distinguishes physical and basic behavioral health from specialized behavioral health. 5.9.1.2.1. Neither the minimum MLR standard (85%) nor the refund applicable to the aggregate MLR shall apply to distinct MLRs reported.	5.9.1.1. An MLR shall be reported in the aggregate, including all medical services covered under the contract, unless LDH requires separate reporting and separate MLR calculations for specific populations. 5.9.1.1.1. If the aggregate MLR (cost for health care benefits and services and specified quality expenditures) or the MLR for any specific population is less than eighty-five percent (85%), the MCO shall refund LDH the difference. Any unpaid balances after the refund is due shall be subject to interest at the current Federal Reserve Board lending rate or ten percent (10%) annually, whichever is higher. 5.9.1.2. LDH may request MLR reporting that distinguishes physical and basic behavioral health from specialized behavioral health. ~~5.9.1.2.1. Neither the minimum MLR standard (85%) nor the refund applicable to the aggregate MLR shall apply to distinct MLRs reported.~~	Assistance Percentage (FMAP), as opposed to the enhanced Expansion FMAP for periods within Federal Fiscal Years 2020 – 2023.
5	5.13.2.2. The MCO shall "pay and chase" the full amount allowed under the MCO payment schedule for the claim and then seek reimbursement from the TPL insurer (within sixty days after the end of the month in which the payment was made) for any liable TPL of legal liability if: • The claim is for prenatal care for pregnant women as defined by HPA 16-17; • The claim is for preventive pediatric services as defined by HPA 16-17; or • The claim is for a service that is provided to an individual on whose behalf child support enforcement is being carried out by the state Title IV-D agency.	5.13.2.2. The MCO shall "pay and chase" the full amount allowed under the MCO payment schedule for the claim and then seek reimbursement from the TPL insurer (within sixty days after the end of the month in which the payment was made) for any liable TPL of legal liability if the claim is for preventive pediatric services, as defined in the **MCO Manual**: • ~~The claim is for prenatal care for pregnant women as defined by HPA 16-17;~~ • ~~The claim is for preventive pediatric services as defined by HPA 16-17; or~~ • ~~The claim is for a service that is provided to an individual on whose behalf child support enforcement is being carried out by the state Title IV-D agency.~~ 5.13.2.3. Effective April 1, 2021, the MCO shall "wait and see" on claims for a service that is provided to an individual on whose behalf child support	These revisions are to comply with the Bipartisan Budget Act of 2018 (Pub. L. 115-123) signed into law on February 9, 2018 which includes several provisions which modify third party liability (TPL) rules related to special treatment of certain types of care and payment and changes made to the Bipartisan Budget Act of 2013 made in April of 2019.

Item	Change From:	Change To:	Justification
		enforcement is being carried out by the state Title IV-D agency. "Wait and see" is defined as payment of a claim only after documentation is submitted to the MCO demonstrating that one hundred (100) calendar days have elapsed since the provider billed the responsible third party and the provider has not received payment for such services. [subsequent provisions renumbered]	
6	[Add new section]	6.19.3.5 Members of the DOJ Agreement Target Population, including those members who are transitioning/have transitioned from a nursing facility or diverted from nursing facility care, shall receive case management services through MCO-contracted community case management agencies upon implementation of the community case management program unless the member declines the service or no longer needs the service as determined through a standardized assessment.	This addition is needed to comply with the DOJ Agreement which requires ongoing community-based case management be provided to members of the target population.
7	6.39.4.6. When OBH determines that nursing facility services are not appropriate, the MCO shall assist eligible members to obtain appropriate alternative behavioral health services available under this contract.	6.39.4.6 When OBH determines that nursing facility services are not appropriate, the MCO shall assist eligible members ~~to obtain~~ with obtaining appropriate alternative behavioral health services available under this contract. The MCO shall make a referral to an MCO-contracted community case management agency under the DOJ Agreement within one (1) business day of referral from LDH.	This revision clarifies the timeframe for the MCO to make referrals for eligible members to community case management services, which is further addressed in new sections 6.19.3.5 and 6.39.8. This requirement will be effective once MCOs provide community case management services as early as July 2021 but no later than October 2021.
8	[Add new section]	6.39.8. Community Case Management Program The MCO shall develop a specialized community case management program consistent with the DOJ Agreement and LDH-issued guidance for the DOJ Target Population transitioning or diverted from nursing facility care, as defined or identified by LDH, using subcontracted community case managers who meet the qualifications established by LDH. The MCO shall maintain	This addition is needed to comply with DOJ Agreement which requires ongoing community-based case management be provided to members of the target population, tracking and monitoring of member outcomes across several domains, tracking and monitoring of member service

Item	Change From:	Change To:	Justification
		ultimate responsibility for ensuring the case management needs of the DOJ Target Population are met by community case managers and community case managers satisfactorily complete required activities.	utilization, and reporting. LDH anticipates the MCOs will provide community case management services as early as July 2021 but no later than October 2021. Additional guidance about the community case management program will be provided in the DOJ Agreement Compliance Guide.
9	**7.3. Geographic Access Requirements** The MCO shall comply with the maximum travel time and/or distance requirements as specified in the Provider Network Companion Guide. Requests for exceptions as a result of prevailing community standards must be submitted in writing to LDH for approval. Such requests should include data on the local provider population available to the non-Medicaid population. If LDH approves the exception, the MCO shall monitor member access to the specific provider type on an ongoing basis and provide the findings to LDH as part of its annual Network Provider Development Management Plan. … **7.3.7. Specialized Behavioral Health Providers** 7.3.7.1. Travel distance to behavioral health specialists (i.e., psychologists, medical psychologists, APRN Nurse Practitioner or Clinical Nurse Specialist (CNS) in mental health, or LCSW's) and to psychiatrists for members living in rural parishes shall not exceed 30 miles or 60 minutes for 90% of such members. 7.3.7.2. Travel distance to behavioral health specialists (i.e., psychologists, medical psychologists, APRN Nurse Practitioner or CNS in mental health, or	**7.3. Geographic Access Requirements** The MCO shall comply with the maximum ~~travel time and/or~~ distance standards ~~requirements~~ as specified in the Provider Network Companion Guide. Requests for exceptions as a result of prevailing community standards must be submitted in writing to LDH for approval. Such requests should include data on the local provider population available to the non-Medicaid population. If LDH approves the exception, the MCO shall monitor member access to the specific provider type on an ongoing basis and provide the findings to LDH as part of its annual Network Provider Development Management Plan. … **7.3.7. Specialized Behavioral Health Providers** 7.3.7.1. Travel distance to behavioral health specialists (i.e., psychologists, medical psychologists, APRN Nurse Practitioner or Clinical Nurse Specialist (CNS) in mental health, or LCSW's) and to psychiatrists for members living in rural parishes shall not exceed thirty (30) miles ~~or 60 minutes~~ for ninety percent (90%) of such members. 7.3.7.2. Travel distance to behavioral health specialists (i.e., psychologists, medical psychologists, APRN Nurse Practitioner or CNS in mental health, or LCSW's) and to psychiatrists for members living in urban parishes shall not	These revisions remove the time standard from the geographic access requirements, as allowed by the managed care final rule published on November 13, 2020, which revised 42 CFR §438.68(b)(1) and (2) by deleting the requirements for states to set time and distance standards and adding a more flexible requirement that states set a quantitative network adequacy standard.

Item	Change From:	Change To:	Justification
	LCSW's) and to psychiatrists for members living in urban parishes shall not exceed 15 miles or 30 minutes for 90% of such members. 7.3.7.3. Travel distance to psychiatric inpatient hospital services shall not exceed 90 miles or 90 minutes for 90% of members. Maximum time for admission shall not exceed 4 hours (emergency involuntary), 24 hours (involuntary), or 24 hours (voluntary). 7.3.7.4. Travel distance to ASAM Level 3.3 shall not exceed 30 miles or 60 minutes for 90% of adult members. Maximum time for admission or appointment shall not exceed 10 business days. 7.3.7.5. Travel distance to ASAM Level 3.5 shall not exceed 30 miles or 60 minutes for 90% of adult members and shall not exceed 60 miles or 90 minutes for adolescent members. Maximum time for admission or appointment shall not exceed 10 business days. 7.3.7.6. Travel distance to ASAM Level 3.7 co-occurring treatment shall not exceed 60 miles or 90 minutes for 90% of adult members. Maximus time for admission or appointment shall not exceed 10 business days. 7.3.7.7. Travel distance to ASAM Level 3.7WM shall not exceed 60 miles or 90 minutes for 90% of adult members. Maximum time for admission or appointment shall not exceed 10 business days. Withdrawal management shall be available within 24 hours when medically necessary. 7.3.7.8. Travel distance to Psychiatric Residential Treatment Facilities (PRTF) shall not exceed 200 miles or 3.5 hours for 100% of members. Maximum time for admission shall not exceed 20 calendar days. Access and adequacy is based on availability of in-state PRTFs unless the MCO provides evidence that indicates an out-of-state provider is clinically appropriate to treat the specific needs of the member.	exceed fifteen (15) miles ~~or 30 minutes~~ for ninety percent (90%) of such members. 7.3.7.3. Travel distance to psychiatric inpatient hospital services shall not exceed ninety (90) miles ~~or 90 minutes~~ for ninety percent (90%) of members. Maximum time for admission shall not exceed four (4) hours (emergency involuntary), twenty-four (24) hours (involuntary), or twenty-four (24) hours (voluntary). 7.3.7.4. Travel distance to ASAM Level 3.3 shall not exceed thirty (30) miles ~~or 60 minutes~~ for ninety percent (90%) of adult members. Maximum time for admission or appointment shall not exceed ten (10) business days. 7.3.7.5. Travel distance to ASAM Level 3.5 shall not exceed thirty (30) miles ~~or 60 minutes~~ for ninety percent (90%) of adult members and shall not exceed sixty (60) miles ~~or 90 minutes~~ for ninety percent (90%) of adolescent members. Maximum time for admission or appointment shall not exceed ten (10) business days. 7.3.7.6. Travel distance to ASAM Level 3.7 co-occurring treatment shall not exceed sixty (60) miles ~~or 90 minutes~~ for ninety percent (90%) of adult members. Maximus time for admission or appointment shall not exceed ten (10) business days. 7.3.7.7. Travel distance to ASAM Level 3.7WM shall not exceed sixty (60) miles ~~or 90 minutes~~ for ninety percent (90%) of adult members. Maximum time for admission or appointment shall not exceed ten (10) business days. Withdrawal management shall be available within twenty-four (24) hours when medically necessary. 7.3.7.8. Travel distance to Psychiatric Residential Treatment Facilities (PRTF) shall not exceed two hundred (200) miles ~~or 3.5 hours~~ for one hundred percent (100%) of members. Maximum time for admission shall not exceed twenty (20)	

Item	Change From:	Change To:	Justification
	7.3.7.9. Request for exceptions as a result of prevailing community standards for time and distance accessibility standards must be submitted in writing to LDH for approval. 7.3.7.10. There shall be no penalty if the member chooses to travel further than established access standards in order to access a preferred provider. The member shall be responsible for travel arrangements and costs.	calendar days. Access and adequacy is based on availability of in-state PRTFs unless the MCO provides evidence that indicates an out-of-state provider is clinically appropriate to treat the specific needs of the member. 7.3.7.9. Request for exceptions as a result of prevailing community standards for ~~time and~~ distance accessibility standards must be submitted in writing to LDH for approval. 7.3.7.10. There shall be no penalty if the member chooses to travel further than established access standards in order to access a preferred provider. The member shall be responsible for travel arrangements and costs.	
10	7.6.3.7. The MCO shall make a good faith effort to give written notice of termination of a contracted provider, within 15 days after receipt of issuance of the termination notice, to each MCO member who received his or her care from or was seen on a regular basis by the terminated provider as specified in 42 CFR §438.10(f)(1) within the past two years.	7.6.3.7. The MCO shall notify its enrollees of provider terminations in accordance with the Marketing and Member Education section of this Contract~~make a good faith effort to give written notice of termination of a contracted provider, within 15 days after receipt of issuance of the termination notice, to each MCO member who received his or her care from or was seen on a regular basis by the terminated provider as specified in 42 CFR §438.10(f)(1) within the past two years~~.	This revision removes duplication. Refer to Section 12.21.1 for notification requirements.

Item	Change From:	Change To:	Justification
11	7.9.1. The MCO shall develop and maintain a provider Network Development and Management Plan which ensures that the provision of core benefits and services will occur [42 CFR §438.207(b)]. The Network Development and Management Plan shall be submitted to LDH when significant changes occur and at least annually. The Network Development and Management Plan shall include the MCO's process to develop, maintain and monitor an appropriate provider network that is supported by written agreements and is sufficient to provide adequate access of all required services included in the Contract. When designing the network of providers, the MCO shall consider the following (42 CFR §438. 68):	7.9.1. The MCO shall develop and maintain a provider Network Development and Management Plan which ensures that the provision of core benefits and services will occur [42 CFR §438.207(b)]. The Network Development and Management Plan shall be submitted to LDH when significant changes occur and ~~at least annually~~ as directed by LDH. The Network Development and Management Plan shall include the MCO's process to develop, maintain and monitor an appropriate provider network that is supported by written agreements and is sufficient to provide adequate access of all required services included in the Contract. When designing the network of providers, the MCO shall consider the following (42 CFR §438. 68):	This revision removes the annual submission of the Network Development and Management Plan. The Specialized Behavioral Health Network Development and Management Plan will remain an annual reporting requirement in accordance with section 7.9.8 and via report 053.
12	7.17.1.3. The MCO must keep an up-to-date pharmacy provider directory on its website for public access. This directory must include, but not be limited to, the following information on all contracted network pharmacies: 7.17.1.3.1. Names, locations and telephone numbers. 7.17.1.3.2. Any non-English languages spoken. 7.17.1.3.3. Identification of hours of operation, including identification of providers that are open 24-hours per day. 7.17.1.3.4. Identification of pharmacies that provide vaccine services. 7.17.1.3.5. Identification of pharmacies that provide delivery services. 7.17.1.4. The MCO must make a hard copy of this directory available to its members upon request. The hard copy must be updated at least annually. The online version should be updated in real time, but no less than weekly. …	7.17.1.3. The MCO must keep an up-to-date pharmacy provider directory on its website for public access. This directory must be web-based machine searchable, web-based machine readable, and mobile-enabled and include, but not be limited to, the following information on all contracted network pharmacies: 7.17.1.3.1. Names, locations and telephone numbers. 7.17.1.3.2. Any non-English languages spoken. 7.17.1.3.3. Identification of hours of operation, including identification of providers that are open 24-hours per day. 7.17.1.3.4. Identification of pharmacies that provide vaccine services. 7.17.1.3.5. Identification of pharmacies that provide delivery services. 7.17.1.4. The MCO must make a hard copy of this directory available to its members upon request. The hard copy must be updated at least ~~annually~~ quarterly. The online version should be updated in real time, but no less than weekly.	These revisions to the pharmacy provider directory and general provider directory conform to the managed care final rule published on November 13, 2020 which revised information requirements in 42 CFR §438.10.

Item	Change From:	Change To:	Justification
	12.14. Provider Directory for Members 12.14.1. The MCO shall develop and maintain a Provider Directory in four (4) formats: 12.14.1.1. A hard copy directory, when requested, for members and potential members; 12.14.1.2. Web-based searchable, web-based machine readable, online directory for members and the public; 12.14.1.3. Electronic file of the directory to be submitted and updated weekly to the Medicaid FI, the Enrollment Broker, or other designee as determined by LDH; for the Enrollment Broker; and 12.14.1.4. Hard copy, abbreviated version upon request by the Enrollment Broker. 12.14.2. The MCO shall utilize LDH-approved templates for its provider directory. 12.14.3. The hard copy directory for members shall be revised with updates at least monthly or no more than 30 days after the receipt of updated provider information. Inserts may be used to update the hard copy directories monthly to fulfill requests by members and potential members. The web-based online version shall be updated in real time, but no less than weekly. While daily updates are preferred, the MCO shall at a minimum submit no less than weekly. The abbreviated hard copy version for the Enrollment Broker will be available to all Medicaid enrollees when requested by contacting the Enrollment Broker. Format for this version will be in a format specified by LDH.	… **12.14. Provider Directory for Members** 12.14.1. The MCO shall develop and maintain a Provider Directory in four (4) formats: 12.14.1.1. A hard copy directory, when requested, for members and potential members; 12.14.1.2. Web-based machine searchable, web-based machine readable, mobile-enabled, online directory for members and the public; 12.14.1.3. Electronic file of the directory to be submitted and updated weekly to the Medicaid FI, the Enrollment Broker, or other designee as determined by LDH; for the Enrollment Broker; and 12.14.1.4. Hard copy, abbreviated version upon request by the Enrollment Broker. 12.14.2. The MCO shall utilize LDH-approved templates for its provider directory. 12.14.3. The hard copy directory for members shall be revised with updates at least quarterly~~monthly or no more than 30 days after the receipt of updated provider information~~. Inserts may be used to update the hard copy directories monthly to fulfill requests by members and potential members. The web-based online version shall be updated in real time, but no less than weekly. While daily updates are preferred, the MCO shall at a minimum submit no less than weekly. The abbreviated hard copy version for the Enrollment Broker will be available to all Medicaid enrollees when requested by contacting the Enrollment Broker. Format for this version will be in a format specified by LDH.	

Item	Change From:	Change To:	Justification
13	**12.21. Notice to Members of Provider Termination** 12.21.1. The MCO shall make a good faith effort to give written notice of a provider's termination to each member who received their primary care from, or was seen on a regular basis by the terminated provider. When timely notice from the provider is received, the notice to the member shall be provided within fifteen (15) calendar days of the receipt of the termination notice from the provider. 12.21.2. The MCO shall provide notice to a member, or the parent/legal guardian and the involved state agency as appropriate, who has been receiving a prior authorized course of treatment, when the treating provider becomes unavailable. The written notice shall be provided within seven (7) calendar days from the date the MCO becomes aware of such, if it is prior to the change occurring. Failure to provide notice prior to the dates of termination will be allowed when a provider becomes unable to care for members due to illness, a provider dies, the provider moves from the service area and fails to notify the MCO, or when a provider fails credentialing or is displaced as a result of a natural or man-made disaster. Under these circumstances, notice shall be issued immediately upon the MCO becoming aware of the circumstances.	**12.21. Notice to Members of Provider Termination** 12.21.1. The MCO shall make a good faith effort to give written notice of a provider's termination to each member who received their primary care from, or was seen on a regular basis by the terminated provider, which shall be defined as one visit within the last eighteen (18) months. When timely notice from the provider is received or when the MCO initiates the termination, the notice to the member shall be provided by the later of thirty (30) calendar days prior to the effective date of the termination, or ~~within~~ fifteen (15) calendar days ~~of the~~ after receipt or issuance of the termination notice ~~from the provider~~. 12.21.2. The MCO shall provide notice to a member, or the parent/legal guardian and the involved state agency as appropriate, who has been receiving a prior authorized course of treatment, when the treating provider becomes unavailable. ~~The written notice shall be provided within seven (7) calendar days from the date the MCO becomes aware of such, if it is prior to the change occurring.~~ Failure to provide notice prior to the dates of termination will be allowed when a provider becomes unable to care for members due to illness, a provider dies, the provider moves from the service area and fails to notify the MCO, or when a provider fails credentialing or is displaced as a result of a natural or man-made disaster. Under these circumstances, notice shall be issued immediately upon the MCO becoming aware of the circumstances.	These revisions conform to the managed care final rule published on November 13, 2020 which revised information requirements in 42 CFR §438.10.
14	12.22.4. Written materials must also be made available in alternative formats upon request of the potential member or member at no cost. Auxiliary aids and services must also be made available upon request of the potential member or member at no cost. Written materials must include taglines in the prevalent non-English languages in the state, as well as large print, explaining the availability of written translation or oral interpretation to understand the	12.22.4. Written materials must also be made available in alternative formats upon request of the potential member or member at no cost. Auxiliary aids and services must also be made available upon request of the potential member or member at no cost. Written materials critical to obtaining services must include taglines in the prevalent non-English languages in the state, as well as large print, explaining the availability of written translation or oral	These revisions conform to the managed care final rule published on November 13, 2020 which revised information requirements in 42 CFR §438.10.

Item	Change From:	Change To:	Justification
	information provided and the toll-free and TTY/TDY telephone number of the MCO's member/customer service unit. Large print means printed in a font size no smaller than 18 point.	interpretation to understand the information provided, information on how to request auxiliary aids and services, and the toll-free and TTY/TDY telephone number of the MCO's member/customer service unit. Large print means printed in a ~~font size no smaller than 18 point~~ conspicuously-visible font size as defined in 45 CFR §92.8(f)(1).	
15	13.2.4.2. The member may file an appeal either orally or in writing. The oral appeal shall be followed by a written, signed appeal unless the member requests an expedited resolution. … 13.4.2.1. Provide that oral inquiries seeking to appeal an action are treated as appeals (to establish the earliest possible filing date for the appeal). The member, member's authorized representative or provider, acting on behalf of the member and with the member's written consent, may file an expedited appeal either orally or in writing. Unless the member requests an expedited appeal, the oral appeal shall be confirmed in writing.	13.2.4.2. The member may file an appeal either orally or in writing. ~~The oral appeal shall be followed by a written, signed appeal unless the member requests an expedited resolution.~~ … 13.4.2.1. Provide that oral inquiries seeking to appeal an action are treated as appeals (to establish the earliest possible filing date for the appeal). The member, member's authorized representative or provider, acting on behalf of the member and with the member's written consent, may file an expedited appeal either orally or in writing. ~~Unless the member requests an expedited appeal, the oral appeal shall be confirmed in writing.~~	The managed care final rule published on November 13, 2020 eliminates the requirement for enrollees to submit a written, signed appeal after an oral appeal is submitted. [Refer to 42 CFR §438.402(c)(3)(ii) and §438.406(b)(3).]
16	16.15 CMS Interoperability and Patient Access The MCO shall be in compliance with the CMS Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issues of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers (referred to as the "CMS Interoperability and Patient Access final rule") no later than July 1, 2021. The MCO shall: 16.15.1 Participate in development meetings as required by LDH.	16.15 CMS Interoperability and Patient Access The MCO shall ~~be in compliance~~ comply with the CMS Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issues of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers (referred to as the "CMS Interoperability and Patient Access final rule") ~~no later than July 1, 2021~~ in accordance with timelines established by CMS and as directed by LDH through the **LDH MCE Interoperability Compliance Plan**. ~~The MCO shall:~~	This update provides flexibility for compliance with current and future interoperability and patient access rules and directs the MCOs to the LDH MCE Interoperability Compliance Plan for specific LDH direction on achieving compliance.

Item	Change From:	Change To:	Justification
	16.15.2 Implement and maintain a standards-based Patient Access application programming interface (API) to make certain health information about Medicaid and CHIP beneficiaries, as defined by CMS, accessible through the API, enabling enrollees to access their health data on their Internet-enabled devices. 16.15.3 Establish a Payer-to-Payer Data Exchange, to comply with enrollee requests to have their health data transferred from payer to payer, no later than January 1, 2022. 16.15.4 Make standardized information about provider networks available via a Fast Healthcare Interoperability Resources (FHIR) based Provider Directory API. The MCO shall provide current provider directory information via an API no later than July 1, 2021. 16.15.5 Make available required data in the United States Core Data for Interoperability (USCDI) residing in health information exchanges or public health agencies as described in 45 CFR 170.213. 16.16.6 Provide members free access to the MCO's API for purposes of the Patient Access and Provider Directory APIs.	~~16.15.1 Participate in development meetings as required by LDH.~~ ~~16.15.2 Implement and maintain a standards-based Patient Access application programming interface (API) to make certain health information about Medicaid and CHIP beneficiaries, as defined by CMS, accessible through the API, enabling enrollees to access their health data on their Internet-enabled devices.~~ ~~16.15.3 Establish a Payer-to-Payer Data Exchange, to comply with enrollee requests to have their health data transferred from payer to payer, no later than January 1, 2022.~~ ~~16.15.4 Make standardized information about provider networks available via a Fast Healthcare Interoperability Resources (FHIR) based Provider Directory API. The MCO shall provide current provider directory information via an API no later than July 1, 2021.~~ ~~16.15.5 Make available required data in the United States Core Data for Interoperability (USCDI) residing in health information exchanges or public health agencies as described in 45 CFR 170.213.~~ ~~16.16.6 Provide members free access to the MCO's API for purposes of the Patient Access and Provider Directory APIs.~~	
17	18.5.1 The MCO shall comply with the required format provided by LDH. Encounter data includes claims paid or denied by the MCO or the MCO's subcontractors for services delivered to enrollees through the MCO during a specified reporting period. LDH collects and uses this data for many reasons such as: federal reporting, rate setting, risk adjustment, service verification, managed care quality improvement program, utilization patterns and access to care, LDH hospital rate setting and research studies.	18.5.1 The MCO shall comply with the required format provided by LDH. Encounter data includes claims paid or denied by the MCO or the MCO's subcontractors for services delivered to enrollees through the MCO during a specified reporting period. Submissions must include, at a minimum, all enrollee encounter data, including allowed amount and paid amount, that the State is required to report to CMS. LDH collects and uses this data for many reasons such as: federal reporting, rate setting, risk adjustment, service	This revision is to comply with the managed care final rule published on November 13, 2020 which requires MCOs to submit to the state the same encounter data that is submitted in T-MSIS submissions to CMS, including allowed amount and paid amount. [Refer to 42 CFR § 438.242(c)(3).]

<table>
<tr><th>Item</th><th>Change From:</th><th>Change To:</th><th>Justification</th></tr>
<tr><td></td><td></td><td>verification, managed care quality improvement program, utilization patterns and access to care, LDH hospital rate setting and research studies.</td><td></td></tr>
<tr><td>18</td><td>18.9.3.3 Annual reports and files, and other deliverables due annually, shall be submitted within thirty (30) calendar days following the twelfth (12th) month of the contract year; except those annual reports that have an explicit deadline provided on the LDH website [link] or are specifically exempted from this 30-calendar-day deadline by this Contract. This Contract will specify the due date of any annual report it exempts from this 30-calendar-day deadline. If the Contract is terminated early, prior to 12/31/2020, the Contractor shall submit reports and other deliverables as specified by LDH in the notice of termination, or as otherwise provided in this contract; and</td><td>18.9.3.3 Annual reports and files, and other deliverables due annually, shall be submitted within thirty (30) calendar days following the twelfth (12th) month of the contract year; except those annual reports that have an explicit deadline provided on the LDH website [link] or are specifically exempted from this thirty (30) -calendar- day deadline by this Contract. This Contract will specify the due date of any annual report it exempts from this thirty (30) -calendar- day deadline. If the Contract is terminated early~~, prior to 12/31/2020~~, the Contractor shall submit reports and other deliverables as specified by LDH in the notice of termination, or as otherwise provided in this ~~contract~~Contract; and</td><td>This revision removes the reference to a specific contract end date to account for extensions of the contract via amendments.</td></tr>
<tr><td>19</td><td>Table of Monetary Penalties<table><tr><th>Failed Deliverable</th><th>Penalty</th></tr><tr><td>Prompt Pay
Ninety percent (90%) of all clean claims must be paid within fifteen (15) business days of the date of receipt.
Ninety-nine percent (99%) of all clean claims must be paid within thirty (30) calendar days of the date of receipt.
The MCO shall pay providers interest at 12% per annum, calculated</td><td>Five thousand dollars ($5,000.00) for the each month that an MCO’s claims performance percentages by claim type fall below the performance standard.

Twenty-five thousand dollars ($25,000.00) for each additional month that the claims performance percentages by claim type, by</td></tr></table></td><td>Table of Monetary Penalties<table><tr><th>Failed Deliverable</th><th>Penalty</th></tr><tr><td>Prompt Pay
Ninety percent (90%) of all clean claims must be paid within fifteen (15) business days of the date of receipt.
One hundred percent (100%) ~~Ninety-nine percent (99%)~~ of all clean claims must be paid within thirty (30) calendar days of the date of receipt.</td><td>Five thousand dollars ($5,000.00) for ~~the~~ each month that ~~an MCO’s~~the claims performance percentages by claim type fall below the performance standard.

Twenty-five thousand dollars ($25,000.00) for each additional month that the claims performance percentages by claim type~~, by~~</td></tr></table></td><td>This revision corrects the monetary penalty associated to align with the prompt pay revision in Amendment 3.</td></tr>
</table>

Item	Change From:	Change To:	Justification
	daily for the full period in which the clean claim remains unadjudicated beyond the 30-day claims processing deadline. Interest owed the provider must be paid the same date that the claim is paid. MCO fall below the performance standards. One thousand dollars ($1,000.00) per claim if the MCO fails to timely pay interest.	• The MCO shall pay providers interest at twelve percent (12%) per annum, calculated daily for the full period in which the clean claim remains unadjudicated beyond the thirty (30) calendar -day claims processing deadline. Interest owed the provider must be paid the same date that the claim is paid. ~~MCO~~ fall below the performance standards. One thousand dollars ($1,000.00) per claim if the MCO fails to timely pay interest.	
20	**25.0 TERMS AND CONDITIONS** The Contract effective date is anticipated to be January 1, 2020. LDH reserves the right to revise the anticipated effective date and/or dates of the enrollment phases to a later date. The term of the contract shall be twelve (12) months from the effective date or unless terminated prior to that date in accordance with state or federal law or terms of the Contract.	**25.0 TERMS AND CONDITIONS** The Contract effective date is anticipated to be January 1, 2020. LDH reserves the right to revise the anticipated effective date and/or dates of the enrollment phases to a later date. The term of the contract shall be twelve (12) months from the effective date or as otherwise extended if mutually agreed to in accordance with Section 25.1, unless terminated prior to that date in accordance with state or federal law or terms of the Contract.	This revision corrects the term of the contract to incorporate extensions of the contract via amendments.
21	**25.18 Entire Contract** This Contract, a continuation of the services provided under the contract resulting from the RFP issued by LDH in 2014 (#305PUR-DHHRFP-BH-MCO-2014-MVA), consists of the following documents, which shall constitute the entire agreement between the parties with respect to the subject matter:	**25.18 Entire Contract** This Contract, a continuation of the services provided under the contract resulting from the RFP issued by LDH in 2014 (#305PUR-DHHRFP-BH-MCO-2014-MVA), consists of the following documents, which shall constitute the entire agreement between the parties with respect to the subject matter:	These revisions will allow LDH to apply non-compliance actions for violations of this Contract that are discovered following termination or expiration.

Item	Change From:	Change To:	Justification
	• The CF-1 and all of its attachments, including this Statement of Work; • RFP #305PUR-DHHRFP-BH-MCO-2014-MVA and addenda; and • The Proposal submitted by the Contractor in response to RFP #305PUR-DHHRFP-BH-MCO-2014-MVA. The MCO shall comply with all provisions of the Contract and shall act in good faith in the performance of the provisions of said Contract. The MCO shall be bound by all applicable Department issued guides. The MCO agrees that failure to comply with the provisions of the Contract may result in the assessment of monetary penalties, sanctions and/or termination of the Contract in whole or in part, as set forth in the Contract. The MCO shall comply with all applicable LDH policies and procedures in effect throughout the duration of the Contract period. The MCO shall comply with all applicable LDH provider manuals, rules and regulations and guides. LDH, at its discretion, will issue correspondence to inform the MCO of changes in Medicaid policies and procedures which may affect the Contract. Unless otherwise specified in the Medicaid correspondence the MCO will be given sixty (60) calendar days to implement such changes.	• The CF-1 and all of its attachments, including this Statement of Work; • RFP #305PUR-DHHRFP-BH-MCO-2014-MVA and addenda; and • The Proposal submitted by the Contractor in response to RFP #305PUR-DHHRFP-BH-MCO-2014-MVA. The MCO shall comply with all provisions of the Contract and shall act in good faith in the performance of the provisions of said Contract. The MCO shall be bound by all applicable Department issued guides. The MCO agrees that failure to comply with the provisions of the Contract may result in the assessment of monetary penalties, sanctions and/or termination of the Contract in whole or in part, as set forth in the Contract. The MCO shall comply with all applicable LDH policies and procedures in effect throughout the duration of the Contract period. The MCO shall comply with all applicable LDH provider manuals, rules and regulations and guides. All provisions of the Contract that are carried over into a new contract survive the termination or expiration of the Contract. Therefore, if, after the termination or expiration of the Contract and during the term of the new contract, LDH discovers that the MCO failed to comply with any provision of the Contract that was carried over into the new contract, LDH may assess monetary penalties, sanctions, and/or terminate the new contract in whole or in part, as set forth in the applicable contract, as explained below. If the entirety of the noncompliance occurred during the term of the Contract, LDH may assess monetary penalties, sanctions, and/or terminate the new contract in accordance with the provisions of the Contract. If the noncompliance occurred partially during the term of the Contract and partially during the term of the new contract, LDH may assess monetary penalties, sanctions, and/or terminate the new contract in accordance with the provisions of the Contract for the portion of the noncompliance that occurred during the term of the Contract and in accordance with the provisions of the	

Item	Change From:	Change To:	Justification
		new contract for the portion of the noncompliance that occurred during the term of the new contract. If LDH cannot reasonably determine which portion of the noncompliance occurred during which contract term, LDH may utilize the Contract for the entirety of the noncompliance. LDH, at its discretion, will issue correspondence to inform the MCO of changes in Medicaid policies and procedures which may affect the Contract. Unless otherwise specified in the Medicaid correspondence the MCO will be given sixty (60) calendar days to implement such changes.	
22	**25.63 Withholding in Last Month of Payment** For the last month of the Contract, the Department shall withhold seventy-five percent (75%) of the final payment to the Contractor for a maximum of one hundred and eighty (180) days from the due date of such amount. LDH may retain and offset this withhold if the outgoing Contractor does not fulfill its contractual obligations, including but not limited to repaying any outstanding monetary penalties and sanctions, or does not repay LDH for payments made on behalf of ineligible recipients, some of which may extend past the term of the Contract.	**25.63 Withholding in Last Month of Payment** For the last month of the Contract, the Department shall withhold seventy-five percent (75%) of the final payment to the Contractor for a maximum of one hundred ~~and~~ eighty (180) days from the due date of such amount. LDH may retain and offset this withhold if the outgoing Contractor does not fulfill its contractual obligations, ~~including, but not limited to,~~ some of which may extend past the term of the contract, including, but not limited to, repaying LDH any outstanding monetary penalties and sanctions assessed during the term of the Contract, repaying LDH monetary penalties and sanctions assessed after the term of the Contract for any Contractor noncompliance that occurred during the term of the Contract but was not or could not have been discovered by LDH prior to Contract termination or expiration, or ~~does not~~ repaying LDH for payments made on behalf of ineligible recipients~~, some of which may extend past the term of the Contract~~.	These revisions will allow LDH to utilize the final payment withhold as payment for penalties or sanctions resulting from violations of this Contract that are discovered following termination or expiration.
23	[Glossary] **Adverse Benefit Determination** – Means any of the following: • The denial or limited authorization of a requested service, including determinations based on the type or level of service,	[Glossary] **Adverse Benefit Determination** – Means any of the following: • The denial or limited authorization of a requested service, including determinations based on the type or level of service,	This revision is to comply with the managed care final rule published on November 13, 2020 which clarifies that a denial due solely to not meeting the definition of a clean claim is not an adverse benefit determination and is therefore not subject to the notice

Item	Change From:	Change To:	Justification
	requirements for medical necessity, appropriateness, setting, or effectiveness of a covered benefit. • The reduction, suspension, or termination of a previously authorized service. • The denial, in whole or in part, of payment for a service. • The failure to provide services in a timely manner, as defined by the State. • The failure of an MCO to act within the timeframes provided in 42 CFR §438.408(b)(1) and (2) regarding the standard resolution of grievances and appeals. • The denial of a member's request to dispute a financial liability, including cost sharing, copayments, premiums, deductibles, coinsurance, and other member financial liabilities.	requirements for medical necessity, appropriateness, setting, or effectiveness of a covered benefit. • The reduction, suspension, or termination of a previously authorized service. • The denial, in whole or in part, of payment for a service. A denial, in whole or in part, of a payment for a service solely because the claim does not meet the definition of a ''clean claim'' in accordance with 42 CFR §447.45(b) is not an adverse benefit determination. • The failure to provide services in a timely manner, as defined by the State. • The failure of an MCO to act within the timeframes provided in 42 CFR §438.408(b)(1) and (2) regarding the standard resolution of grievances and appeals. The denial of a member's request to dispute a financial liability, including cost sharing, copayments, premiums, deductibles, coinsurance, and other member financial liabilities.	requirements of 42 CFR §438.404. [Refer to 42 CFR §438.400(b)(3).]
24	**LIST OF MCO COMPANION GUIDES** **…** **13. MCO Manual**	**LIST OF MCO COMPANION GUIDES** **…** **13. MCO Manual** **14. LDH MCE Interoperability Compliance Plan**	The LDH MCE Interoperability Compliance Plan provides operational guidance on current and future interoperability and patient access rules.