Report on Establishment of New Opioid Treatment Programs

Response to House Concurrent Resolution No. 71 of the 2019 Regular Legislative Session

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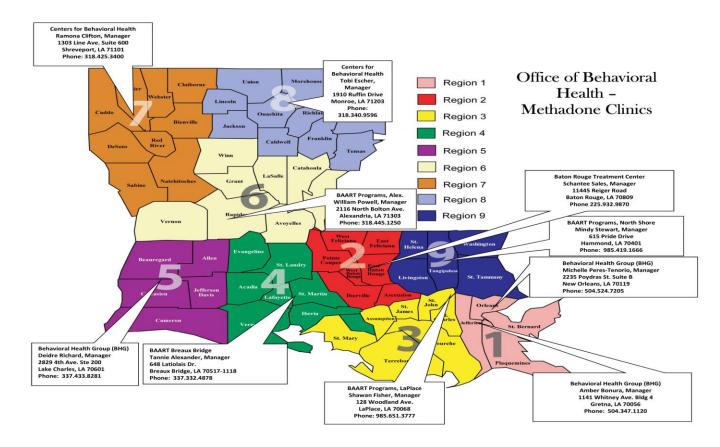
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Background

Methadone is a synthetic analgesic drug that is similar to morphine in its effects, but longer acting, and used in the treatment of opioid addiction (e.g., prescription painkillers, heroin). Methadone is a prescribed medication and operates to normalize brain chemistry, blocking the euphoric effects of opioids, relieving physiological cravings and normalizing body functions without the negative effects of the abused drug. Methadone treatment programs detoxify individuals with opioid use disorder (OUD) using a synthetic narcotic to achieve recovery with counseling and supportive services.

Opioid Treatment Programs (OTPs) have been established in Louisiana since the early 1970s. The Narcotics Rehabilitation Commission initially established and directed the pilot clinic programs for the administration of methadone under medical supervision. By the 1980s, this oversight transferred to the Office of Prevention and Recovery from Alcohol and Drug Abuse in the Department of Health and Human Resources, which was designated as the State Methadone Authority.

In 2001, Act 774 enacted a Moratorium on Methadone licenses through July 1, 2010. At the conclusion of the moratorium, the Office of Behavioral Health (OBH), previously named the Office for Addictive Disorders, conducted a Needs Review and issued a Request for Application in accordance with administrative rules. During the moratorium, there were eight (8) OTPs in Louisiana, with two additional applications approved after the review process was instituted and then subsequently licensed by the state. Those 10 OTPs remain open as of 2020, and one is located in each of the 9 LDH administrative regions of the state:



Each provider is privately owned and operated. The OTPs must maintain approval by the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Drug Enforcement Administration (DEA), accreditation by a SAMHSA-approved accrediting body, and licensure by the LDH Health Standards Section and the Board of Pharmacy. OTPs adhere to licensure requirements¹ for Behavioral Health Service Providers (BHSP), in addition to specific requirements for OTPs. The State Opioid Treatment Authority (SOTA), who is a staff member of OBH, provides programmatic oversight of the OTPs to ensure treatment of services adhere to state and federal regulations as well as offer quality services to participants.

Act 308 in the 2013 Regular Session created a single license for behavioral health service providers, including the OTPs. This act also prohibited the department from licensing any new OTPs unless the department determines a need for another OTP in a certain geographic location.

Effective January 20th, 2020, Methadone is covered by Medicaid for OUD treatment. The State Plan was amended to reflect this change and was subsequently approved by CMS. A provider subspecialty code 8V was established for the OTP clinics as sole source providers. Using other states as a model, a bundled rate was developed to reimburse for OTP services. Bundled rates for the OTPs facilitate the practical needs of patient-centered treatment in the administration of Medication-Assisted Treatment (MAT) to integrate the provision of counseling and medical services. MAT strengthens recovery and decreases recidivism in patients diagnosed within the substance use disorder (SUD) spectrum. This rate is inclusive of the behavioral health treatment components, physical examinations and laboratory services, and ancillary services offered by the OTPs. Prior to Medicaid coverage, this was a self-pay cash business (or OBH grant funded) for every client.

Task At Hand

Need to Expand

Nationally, opioid abuse and addiction has been a topic of concern in recent years. According to the United States Department of Health and Human Services, more than 130 Americans died every day from opioid-related drug overdoses, while estimating 2 million Americans had an OUD in 2018.² In Louisiana, opioids accounted for 34 percent of the total drug overdose deaths in 2018, and overall opioid deaths have increased from 217 in 2014 to over 400 in 2018.³ There were 7,868 Emergency Room admits related to opioids in State Fiscal Year 2018, with Medicaid costs exceeding \$1.8 million. Further, there were 9,834 hospital admissions in State Fiscal Year 2018, with Medicaid costs exceeding \$39.7 million. Given the landscape, the Louisiana Legislature recognized the need for a state-level response and passed House Concurrent Resolution No. 71.

House Concurrent Resolution No. 71 of the 2019 Regular Session, passed on June 14th, 2019, requests LDH to issue guidance to allow the establishment of new opioid treatment programs by December 31, 2020. As part of this charge, LDH assembled a working group to study the issue and make

https://www.hhs.gov/opioids/sites/default/files/2019-11/Opioids%20Infographic letterSizePDF 10-02-19.pdf

http://ldh.la.gov/assets/docs/BehavioralHealth/HOPE/HOPE 2019 End of Year Report.pdf

¹ https://ldh.la.gov/assets/medicaid/hss/docs/BHS/LAC 48 1 CH 56 BHSP.pdf

² The Opioid Epidemic By The Numbers:

³ 2019 HOPE Council Year End Report:

recommendations. That working group convened on August 28th, 2019, and consisted of representatives from OBH and the Office of Public Health (OPH) as well as consultations with other departments of LDH.

Workgroup discussions focused on a wide variety of aspects of the Opioid Treatment Programs in Louisiana. Each workgroup meeting facilitated discussion from all workgroup members and focused on brainstorming the best method to expand as well as identifying the areas of the state most in need of additional OTPs.

Requirements to Expand

As mentioned previously, LDH is currently prohibited from licensing any new OTPs unless the department determines a need for another OTP in a certain geographic location. The process for determination of need and applicant review is outlined in Louisiana Administrative Code 48:I.12901-12913⁴. An offsite location and/or a mobile site of an existing OTP clinic is considered a new OTP and, as such, must receive approval from the department.

A summary of this need and application review includes the following steps:

- The department shall conduct an OTP need review to determine if there is a need for new or additional opioid treatment programs in a certain geographic location.
- Once the need has been determined, the department will issue a request for applications for new or additional OTPs.
- The department shall conduct an OTP application review.
- Once the application review approval is granted, the OTP is then eligible to apply for a license from the department.
- No later than one year from the date of the OTP application review approval, the OTP shall achieve BHSP licensure and shall be in compliance with all applicable OTP federal, state, and local laws and regulations.

OTPs must comply with a rigorous approval process from multiple authorities at both the federal and state levels. This includes:

- Certification from <u>SAMHSA's Division of Pharmacologic Therapies (DPT)</u>;
- Accreditation from a <u>SAMHSA-approved accrediting body</u> (e.g., The Joint Commission, Council on Accreditation, or CARF International);
- Registration and approval with the <u>Drug Enforcement Administration (DEA)</u>;
- Pharmacy and Controlled Dangerous Substance (CDS) Licensure from the <u>Louisiana Board of</u>
 Pharmacy;
- Licensure from the LDH Health Standards Section; and
- Approval from the State Opioid Treatment Authority (SOTA).

Considerations For New OTP Providers

Approximately 30 percent of adults with a chronic physical health condition also have one or more behavioral health conditions, such as anxiety disorders, panic disorders, mood disorders, or SUD. Though these conditions are inextricably linked, health care providers often assess and treat patients with physical

⁴ https://www.doa.la.gov/Pages/osr/LAC-48.aspx

health conditions and behavioral health conditions in silos.⁵ Further, studies have shown integrating care can lead to improved patient outcomes and lower costs.⁶

Drug and alcohol use-related stigma affects employment, physical and mental health, and has been shown to be a barrier to seeking treatment. Stigma leads to negative impacts on quality of life, alcohol/substance use, and other depressive symptoms. There are largely three main factors related to the stigma associated with SUD:

- The understanding of OUD as a medical illness is still overshadowed by its misconception as a moral weakness or a willful choice.
- The separation of OUD treatment from physical health means clinicians overlook other health issues.
- Loaded language, which are words or phrases with strong connotations associated with invoking an emotional response and/or exploiting stereotypes, can further the stigma associated with the condition. People may feel judged for being in treatment and thus less likely to remain in treatment.

Given what we know about the benefits of integrated care and the challenges associated with methadone use stigma, LDH believes the best course for OTP expansion is likely an integrated setting via a federally qualitified health center (FQHC), a Rural Health Clinic (RHC), or integrated health center. Given the current crisis and the need to increase the number of OTPs, we would also consider existing OTP programs that have a proven track record of success.

FQHCs

An FQHC provides health care services typically included as part of a physician's medical practice. Services and supplies that are furnished by FQHC staff or as an incident to an FQHC professional service are considered part of the FQHC service. An FQHC provides services under an agreement with a federal department/agency pursuant to federal law and regulation and pursuant to the provider's approved scope of work for ambulatory services. An FQHC that may chose to provide services such as operation of an OTP clinic, which is separate from an agreement with a federal department/agency pursuant to federal law and regulation and separate from its approved scope of work for ambulatory services, is required to obtain a BHSP license issued by LDH's Health Standards Section. In a situation where an FQHC may be interested in operating an OTP, the entity would also enroll as an appropriate Specialized Behavioral Health Services (SBHS) provider type with a unique National Provider Identifier (NPI), shall have active BHSP licensure issued by LDH Health Standards, and shall bill under its unique BHSP NPI in accordance with the Behavioral Health Medicaid Rules, Policies, and Manuals.

RHC

The RHC program was established through the (RHC) Act of 1977 to address an inadequate supply of primary health care providers who serve Medicare and Medicaid beneficiaries in rural areas. The program provides qualifying clinics located in rural and medically underserved communities with a prospective reimbursement methodology described under Section 1902(bb) of the Social Security Act.

⁵ Effectiveness and Value of Integrating Behavioral Health Into Primary Care https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2513443

⁶ Integrated Care Delivery May Bring Better Outcomes, Lower Costs https://healthitanalytics.com/news/integrated-care-delivery-may-bring-better-outcomes-lower-costs

RHCs may be either provider-based clinics or independent clinics. The provider-based RHC is considered an integral part of a rural hospital, nursing home or home health agency that is a Medicare-certified provider. An independent RHC is any other clinic that meets the requirement to be classified as an RHC and is owned and operated by any entity as long as it is not operated as a rehabilitation agency or a facility primarily for care and treatment of mental diseases.

In order to become licensed, an RHC must meet rural and Health Professional Shortage Area requirements and eligibility criteria. Those <u>eligibility requirements</u> include certification by the Louisiana Department of Health.

There are 3 ways that an RHC can be licensed and certified in Louisiana:

- An independently licensed RHC that is independently certified as an RHC;
- An independently licensed RHC that is certified as an independent RHC but provider based to the hospital; or
- An RHC that is licensed as an outpatient department of the hospital, certified as an independent RHC but provider based to the hospital.

In a situation where an RHC may be interested in operating an OTP, the entity would need to comply with the dual requirements of operation.

Existing OTPs

Louisiana's current OTPs are an option for expansion in underserved areas. The experience and learning curve of existing OTPs make them a potentially attractive option for new OTP locations, although development in new areas would still require the same process as a new provider without a current OTP presence.

The methadone clinic model was carved into law in the United States in 1974 when Congress passed the Narcotic Addiction Treatment Act. The last time Congress expanded access to medication approved for opioid use disorder was when it passed the Drug Addiction Treatment Act of 2000. It allowed prescribers to utilize buprenorphine in their offices, also known as office-based opioid treatment programs which increased access to treatment. However, the barriers to the delivery of methadone such as diversion, stigma and overdose remain intact.

As previously stated, Louisiana's landscape consists of the 10 existing OTPs with one in each region of the state. Each facility is privately owned and operated serving approximately 3,000 – 4,000 patients per month during the last six (6) years. When considering Medicaid expansion and reimbursement for Methadone as treatment for SUD, it is important to note that the clinics neither operate at capacity nor have waiting lists for admission at this time. Methadone clinics utilize the same protocol for both Buprenorphine and Methadone which substantially reduces recidivism. Although there has been discussion of "satellite" clinics, currently the DEA does not license satellite clinics. Other states who have satellite clinics were allowed to maintain them as a grandfather clause situation.

In addition, not all existing OTPs may be ideal for new locations given the need for smooth implementation and navigation of a sometimes controversial service model in communities. Existing OTPs in which there have been investigations by LDH Health Standard Section, which has programmatic oversight of licensure for all health care personnel and facilities, may not be chosen to expand. Further, existing OTPs for which LDH has issued documentation of the need for quality improvement would also be discouraged. In

alignment with current trends, LDH would also like to see deeper integration with primary care health services as well.

The Department seeks to solidify and expand access to patient-centered quality services in which national best practices are used to attain positive outcomes and continued treatment. Expanding with existing OTP providers who have proven outcomes would increase access to quality treatment and meet the treatment needs of Louisiana citizens in an expedited fashion.

Expansion Locations

Given the vulnerable population served in OTPs and the extensive requirements on the state and federal level of operating a methadone clinic, LDH acknowledges careful progression is needed to expand the number of clinics in Louisiana. LDH will phase in growth of OTP clinics under the following parameters.

Current Landscape

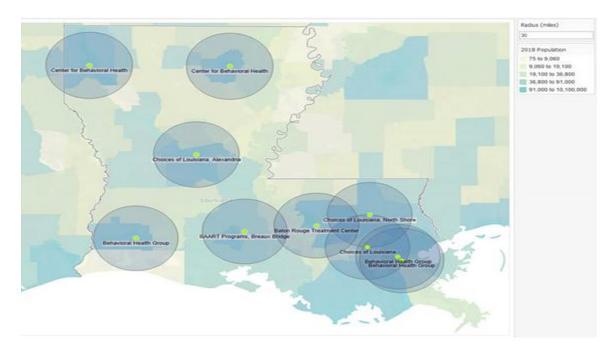
The state of Louisiana totals 43,562 square miles of non-wetland landmass and a 2019 estimated population of 4.6 million⁷. Approximately 56 percent of the state's landmass is considered rural, as is roughly 25 percent of the Louisiana population.⁸

The burden of this geographic distance is especially difficult given the intensity of the onsite program. Federal and state authorities set certain requirements on the various treatment phases for methadone patients. During the initial months of early stabilization and treatment, patients must travel daily to the clinic to receive their daily dosing of methadone. Patients also participate in weekly monitoring by the nursing staff, individual and group counseling sessions, and drug screen testing. During the maintenance phase, patients may be approved to receive take-home dosing of methadone treatment, which still requires weekly visits to the clinic.

The 10 current OTPs are located mainly in metropolitan areas of Louisiana. Drive time from rural parishes into the cities can be an hour or more, and may be exacerbated by traffic patterns. The visual below shows the current OTP locations, along with the area within a 30-mile radius shaded for context of geographic areas. It demonstrates the significant travel required from some parts of the state to existing OTPs.

⁷ Census.gov: https://www.census.gov/quickfacts/fact/table/LA,US/PST045219

⁸ Economic Research Service: https://www.ers.usda.gov/webdocs/DataFiles/53180/25573 la.pdf?v=0



Phase One Expansion

Given the above realities, LDH conducted a needs assessment for expansion in conjunction with regularly scheduled internal conversations on HCR 71.

This needs assessment was developed based on data collected from the Louisiana Opioid Data and Surveillance System (LODSS), an initiative developed to map and monitor Louisiana's opioid problem. This system was made possible through a partnership between the LDH Office of Public Health, Bureau of Health Informatics and the CDC National Center for Injury Prevention and Control, Cooperative Endeavor Agreement. In addition, the SOTA cross-referenced this data with opioid travel exemption requests, a tool by which a participant may request to receive a limited amount of take home doses to self-administer, which are granted when it is determined a patient's travel time places an undue burden on their recovery. In the Department's view, areas receiving a large number of travel exemption requests are prime areas to consider OTP expansion.

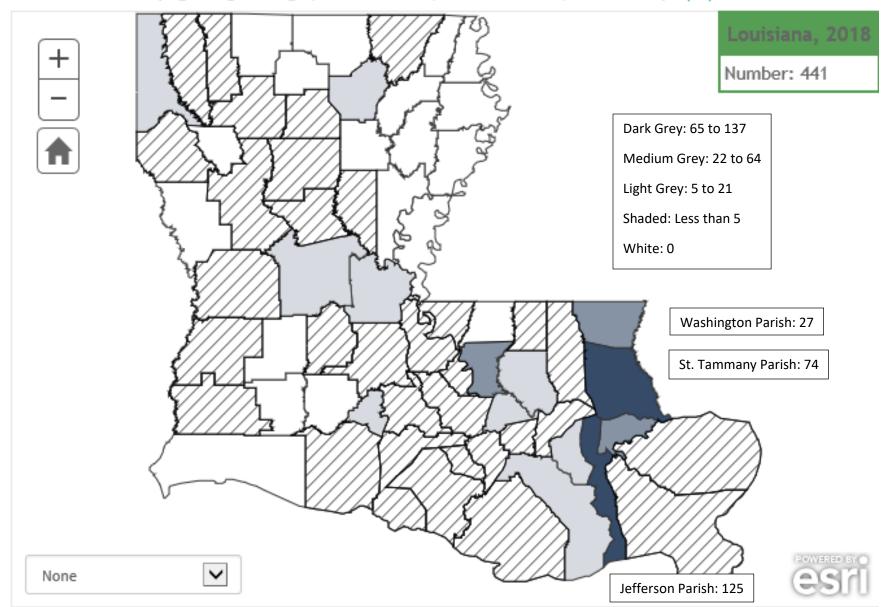
Through that needs assessment, the department determined the first round of OTP expansion should include areas of the state that are geographically distant from current OTP locations, show trends of OTP travel exemption requests submitted to the SOTA, and have high numbers in the following categories:

- 2018 opioid-related deaths based on residence;
- 2018 opioid-related emergency department visits; and
- 2018 opioid-related non-Emergency hospital admissions.

Death > All opioid-involved deaths (residence) > Number



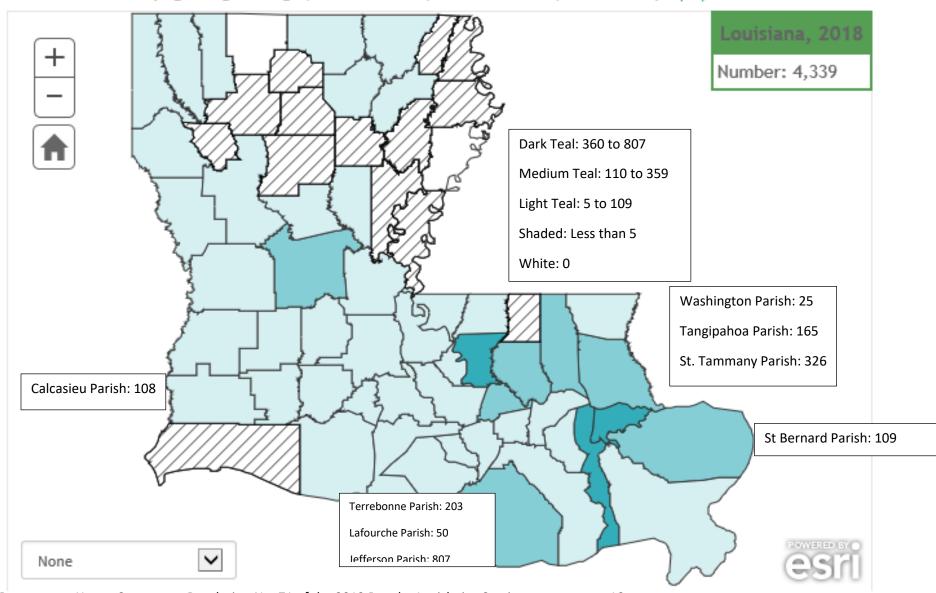
Selected Year: 2018, Age Range: All Ages, Race: All Races, Sex: All Genders, Areas: multiple(64)



Emergency Department > All opioid poisoning-related visits > Number



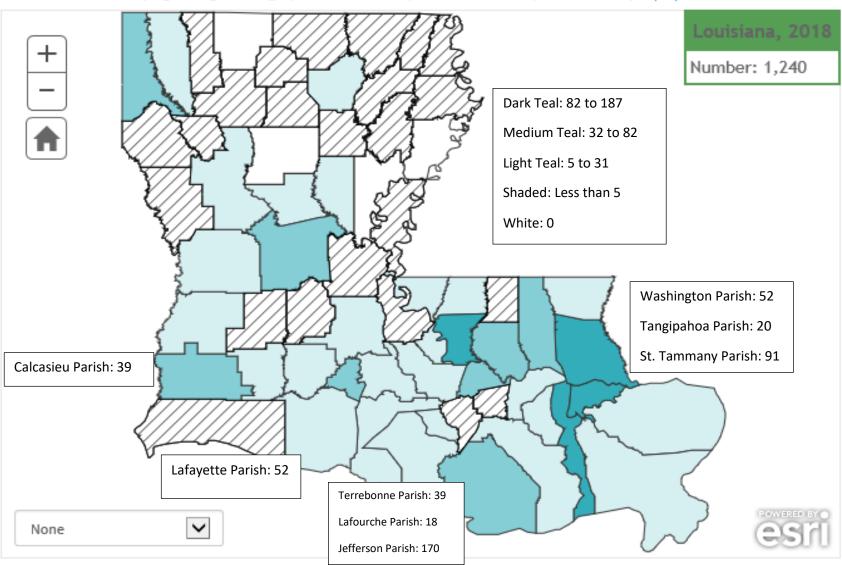
Selected Year: 2018, Age Range: All Ages, Race: All Races, Sex: All Genders, Areas: multiple(64)



Hospital Admissions > All opioid poisoning-related visits > Number



Selected Year: 2018, Age Range: All Ages, Race: All Races, Sex: All Genders, Areas: multiple(64)



Based on these factors, the LDH needs assessment determined immediate OTP expansion should occur in the Washington Parish area as well as in the southern central region of the state in the Terrebonne/Lafourche parish areas. Washington Parish ranks #1 in all four of the above listed metrics among areas that do not currently have an OTP within 30 miles, while the Terrebonne/Lafourche parish areas were found to also consistently rank next highest based on that criteria and distance from current OTPs.

While there are other areas of the state that are more geographically distant from an existing OTP, the data showed there was not a sufficient need to support an additional OTP at this time. These areas will continue to be monitored for the next phase of OTP expansion.

Phase Two Expansion

While the data conveys an immediate need for OTP expansion in the Washington Parish area as well as the Terrebonne/Lafourche Parish region, LDH recognizes there will likely be an additional need for OTP expansion into 2021 and beyond.

In early 2020, Medicaid began covering methadone for patients with a diagnosis of OUD and/or SUD. Medicaid coverage of methadone for OUD is anticipated to alter the landscape of treatment in the state by increasing access to treatment. That initial encounter data for calendar year 2020 and subsequent years, along with updated LODSS system, will serve as the driver for the next needs assessment to determine phase two expansion priorities. LDH will use that opportunity to focus on regions without a current OTP, as well as to examine current OTP capacity for potential expansion in regions that are at or near capacity.

Next Steps and Timeline

Chapter 129 of the Louisiana Administrative Code sets out the requirements the department must take in order to expand the state's Opioid Treatment Program (OTP). LDH will, upon completion and submission of this report and needs assessment, issue a solicitation of interest to add a new OTP in Washington Parish area as well as in the southern central region of the state in the Terrebonne/Lafourche parish areas. That solicitation will:

- Detail the specific need;
- Provide for the application process and application forms; and
- Provide timelines.

LDH will convene an OTP committee, consistent with the requirements listed in Subsection C of Chapter 129 of the Louisiana Administrative Code. This committee will review each submitted application that meets requirements set out by the department in the solicitation of interest and consistent with the aforementioned Chapter 129.

Conclusion

As detailed in this report, changes in the misuse of opioids in the state of Louisiana has necessitated the need for an expansion of the state's Opioid Treatment Program. The Department conducted a needs assessment consistent with legislative requirements and has determined the Washington Parish area, as well as the southern central region of the state in the Terrebonne/Lafourche parish areas, are the two areas most appropriate for an initial expansion of this program. LDH will continue to analyze opioid usage trends with an eye toward future expansion opportunities in 2021 and beyond.

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