

The Chronic Liver Disease Foundation (CLDF) is a nonprofit organization led by liver disease specialists who, for the past 18 years, have been committed to raising awareness of the effects of CLD and have recognized the critical importance of instituting system-wide change. To do so, they recently formed the "CLDF Health Outcomes Coalition," comprised of stakeholders with expertise in liver disease, pharmacoeconomics, public health, health outcomes, managed care organizations, and innovative models of chronic care. The coalition met at the March 2022 Liver Connect Conference and held a 3-hour state-of-the-art symposium to address current issues in the management of cirrhosis from overall health outcome and managed care perspectives.

Symposium: Impact of Chronic Liver Disease on Healthcare Systems

The following presentations were included in the morning symposium:

| Clinical and Economic Impact of Chronic Liver Disease and Cirrhosis on the US Healthcare System | Robert Wong, MD Division of Gastroenterology and Hepatology Veterans Affairs Palo Alto Health Care System Stanford University School of Medicine Palo Alto, CA |
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| Chronic Care Management Approaches in Chronic Liver Disease | Elliot Tapper, MD Associate Professor Division of Gastroenterology and Hepatology University of Michigan Ann Arbor, MI |
| Management Gaps in the Treatment of Chronic Liver Disease | Nancy Reau, MD The Richard B. Capps Chair of Hepatology Professor, Department of Internal Medicine, Division of Digestive Diseases and Nutrition, Rush Medical College Section Chief, Hepatology Associate Director of Organ Transplantation Chicago, IL |
| The Prevention of Rehospitalization of the Chronic Liver Disease Patient | Kimberly Brown, MD Professor of Medicine, Wayne State University Chief, Division of Gastroenterology and Hepatology Associate Medical Director, Henry Ford Hospital Transplant Institute Henry Ford Hospital Detroit, MI |

| Chronic Liver Disease and the Burden on Community Practice | Marcelo Kugelmas, MD Director of Hepatology and Research South Denver Gastroenterology, PC Englewood, CO Timothy Ritter, MD Senior Medical Director, Department of Research and Education Assistant Professor of Medicine, TCU/UNTHSC School of Medicine GI Alliance Research Southlake, TX |
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| Chronic Liver Disease Quality Assurances and Indicators for the Practicing Healthcare Provider | Fasiha Kanwal, MD, MSHS Professor of Medicine Chief, Section of Gastroenterology and Hepatology Baylor College of Medicine Houston, TX |
| Innovative Models of Chronic Liver Disease Care | Ziad Gellad, MD, MPH Associate Professor of Medicine Associate Vice Chair, Ambulatory Services, Department of Medicine Duke University Medical Center Durham, NC |

Following the symposium, the coalition convened a multidisciplinary expert panel to discuss the issues presented, identify critical gaps, and discuss educational and other potential opportunities. This is the first expert panel of its kind with participants carefully chosen based on their experience and tenure. Nine CLDF faculty members and eight managed care advisors were invited to this select meeting, representing academic health systems, private practices, group purchasing groups, integrated delivery networks (IDNs), pharmacy benefit managers (PBMs), regional health plans, and state Medicaid programs.

The aforementioned CLDF faculty members presented in the morning's symposium and participated in the coalition meeting, which was moderated by Marcelo Kugelmas, MD, Director of Hepatology and Research, South Denver Gastroenterology.

Advisors were invited based on their respective expertise in managed care and experience across the industry. The following advisors attended the morning symposium and participated in the coalition meeting:

- Jeff Dunn, PharmD, MBA, Chief Clinical Officer, Cooperative Benefits Group (CBG)
 - CBG is an infrastructure company that provides PBM and clinical pharmacy services to businesses (employer groups/coalitions and health plans/ systems)

- Christopher Goff, JD, MA, Chief Executive Officer & General Counsel, Employers Health Purchasing Corporation of Ohio
 - Represents 300 self-insured employers in 37 states, covering nearly 1.5 million lives
- Eduardo Kneler, MD, Medical Consultant, Department Health Care Services, State of California
 - Represents 14 million Medicaid lives in the state of California
- Dan Kus, RPh, Vice President, Pharmacy Services, Henry Ford Health System
 - The Henry Ford health plan covers more than 570,000 lives across all lines of business
- Myla Maloney, MBA, BCMAS, Chief Commercial Officer, Applied Sciences, Premier Inc.
 - Represents 4,400 hospitals and health systems and 225,000 non-acute sites
- Vishal Patel, MD, Mission Hospitalist Consulting Service, Inpatient Medicine, St. Joseph Health
 - Part of a health system that covers approximately 1.9 million lives
- Ralph J. Riello III, PharmD, BCPS, Clinical Pharmacy Specialist, Clinical & Translational Research, Yale University School of Medicine
 - Delivers advanced care in more than 100 subspecialities and averages 2.6 million patient encounters annually
- Michael Thompson, FSA, MAAA, CEO, National Alliance of Healthcare Purchaser Coalitions
 - Its 45 employer coalition members represent the private and public sector and collectively cover more than 45 million lives

For greater insight into the managed care advisor backgrounds, please see Appendix A.

Symposium Review

The prevalence of chronic liver diseases (CLDs) has fundamentally changed over the last 30 years. As Dr. Robert Wong pointed out during the Cirrhosis Health Outcomes Summit, compared to 1988-94, the prevalence of chronic hepatitis C virus infection (HCV) decreased by 42% in 2013-2016; however, the prevalence of non-alcoholic fatty liver disease (NAFLD) has increased by 60%, and alcoholic liver disease (ALD) has increased by 27% over the same period. Indeed, NAFLD/NASH and ALD are now the major drivers of CLD.¹ Moreover, Dr. Nancy Reau added that, between 2015 and 2030, NAFLD and NASH are projected to increase 21% and 63%, respectively.² She also noted that NAFLD and NASH make up more than 40% of all patients with liver disease for both specialists and primary care providers.

Unlike many other chronic diseases, CLD is particularly prevalent in young adults. Dr. Reau reminded us that CLD causes more deaths than stroke or diabetes in those aged 25 to 54 years. As Dr. Wong highlighted from a BMJ paper by Tapper and Parikh, CLD mortality in younger adults appears to be driven mostly by ALD.³



Figure 1. Effect of COVID-19 on CLD

While these results were published in 2018, the situation has only worsened with the arrival of COVID-19. Dr. Wong pointed to a study by Anderson et al. identifying a marked increase in new liver transplant waiting list registrations for alcohol hepatitis starting in April 2020, which coincided with marked increase in alcohol sales (Figure 1).⁴

Cirrhosis, the common final pathway of all CLDs, became far more deadly starting in 2010 (Figure 2). The increased rates of CLD and onset at a relatively young age led to extraordinary healthcare costs. From 2012 to 2016, CLD hospitalizations increased by 23%, and hospitalization costs rose by 26%,⁵ costs that almost certainly continued to rise in subsequent years. Total direct costs are estimated to be over \$103 billion per year.⁶





Figure 2. Cirrhosis-Related Mortality

Dr. Marcelo Kugelmas pointed out that healthcare providers are "victims of our own success." Patients with CLD are younger, living longer, and require longer periods of chronic care. Unfortunately, demand for care has outpaced the number of properly trained providers. Community care falls into the purview of GI clinics, which are geared more towards ambulatory endoscopy than clinic services.7 Causing this burden is the fact that, once a patient reaches end-stage liver disease, their plight is irreversible. However, Dr. Kugelmas suggests that providers follow the Project ECHO approach that worked so well for HCV.⁸ He also pointed to the OSCAR study, which showed integrating a system for assessing metabolic and liver risk factors, and assessing the Fatty Liver Index (FLI) and Fibrosis-4 score (FIB-4), can be integrated into the current colonoscopy workflow to detect substantial amounts of underdiagnosed liver disease.9

One practice improvement that could make a real and rapid improvement in CLD care is greater awareness and application of CLD guidelines. Shockingly, Dr. Reau mentioned research suggesting 39% of providers are unaware of or unable to name national guidelines for the management of CLD. Approximately half are not currently using AASLD guidelines to manage CLD, including a surprising one-third of specialists. Survey respondents suggested one of the most promising ways to improve guideline use is to take a multidisciplinary approach to CLD care. Providers learn from and change their practices based on exposure to clinical data, thought leader presentations, and reviews of care plans laid out by specialist consultants.

Dr. Kimberly Brown posited that great strides could be made in reducing hospitalization and re-hospitalization if providers simply followed current care guidelines like those from the AASLD. She stated that patients with cirrhosis have high rates of readmission, ranging from 14% at one week to 75% at one year following discharge. The causes of readmission are often related to infection, hepatic encephalopathy, GI bleeding, or metabolic derangements.¹⁰ However, risk of readmission can be accurately estimated at the time of

discharge, Dr. Kimberly Brown pointed out, and steps taken at and soon after discharge can reduce re-hospitalization rates. For example, Dr. Brown highlighted a study, Singal et al. in *Clinical Gastroenterology and Hepatology*, in which factors such as the number of admissions in the prior year, the number of address changes in the prior year, Medicaid insurance, MELD score, and hyponatremia could accurately risk stratify and predict a patient's risk of 30-day readmission (Figure 3).¹¹



Figure 3. Risk of 30-day Readmission after Cirrhosis Hospitalization

While we have frustratingly few data to determine which interventions can reduce readmission, Dr. Brown suggested it is reasonable that implementing guideline-driven quality measures is an excellent place to start. Simply performing an EGD in people with GI bleeding, for example, may decrease 30-day readmission from 35% to 25%.¹² Likewise, primary prophylaxis for low-protein ascites delays readmission and improves survival, and oral antibiotic prophylaxis reduces short-term mortality.¹³ Importantly, Dr. Brown noted that treating hepatic encephalopathy with rifaximin cuts readmissions in half.¹⁴

Dr. Fasiha Kanwal mentioned that we cannot meaningfully improve care if we do not accurately measure it, yet CLD seems to be an ideal candidate for measuring and improving quality of care; it is common, effective treatments exist, and quality-of-care gaps are known. Dr. Kanwal went on to describe the systematic approach that she and others have taken to establish a set of explicit quality-of-care indicators in patients with cirrhosis.¹⁵ This and later efforts led to 26 process measures, seven clinical outcomes, and 13 patientreported outcomes that can be used to guide cirrhosis care and to assess its quality.¹⁶

Several of the experts described new and innovative approaches to improving CLD and cirrhosis care while reducing their cost impact of healthcare systems. Dr. Elliot Tapper reviewed the benefits of several novel approaches to screening and care. With intelligent liver function testing (iLFT), for example, the primary care provider simply



orders LFTs as is common and routine. Abnormal LFT results, however, trigger a series of reflexive tests.¹⁷ Just as importantly, the results are presented to the provider along with a management plan based on advanced testing results. iLFT is a highly cost-effective way to improve liver disease screening and quality of care (Figure 4).¹⁷



Figure 4. Intelligent Liver Function Testing

Dr. Tapper also pointed to the benefits of so-called "hotspotting," which is the use of a specialized care management team for patients at particular risk. This approach has the potential to reduce 30-day readmissions. all-cause and liver-related mortality, and treatment costs.18 In the example, the specialized care management team is comprised of skilled healthcare providers capable of providing on-demand procedures (e.g., EGD) and behavioral interventions, such as alcohol cessation and relapse prevention treatment. Dr. Tapper's focus on behavioral as well as medical aspects of care served as an excellent segue into a presentation of data showing the success of advanced practice providers (APPs) in hepatology.¹⁹ Based on results from natural real-world studies, care by APPs resulted in greater screening for hepatocellular carcinoma and varices. and also more frequent rifaximin use in patients with hepatic encephalopathy at time of discharge. Some evidence also suggested that APP involvement reduced costs and possibly lowered patient mortality.19

Dr. Timothy Ritter shared his experiences with GI Alliance, a large single-specialty group with approximately 700 gastroenterologists and 300 APPs all using a common EMR platform. Currently, each site functions independently, and there are no common protocols for high volume or high-risk patients. However, Dr. Ritter stated that this situation also provides an opportunity. By creating an enterprise-level data warehouse with dashboards for common disease states, the care system can define value, formalize care paths, educate providers, and measure outcomes. Dr. Ritter used a NASH medical home as an example, in which all patients with suspected NASH are screened and the care pathway customized to the patient's level of liver fibrosis or fibrosis risk.

Similarly, Dr. Ziad Gellad pointed to the benefits gained by implementing an inflammatory bowel disease (IBD) medical home supported by a novel mobile health platform called SonarMD.²⁰ The IBD medical home incorporates nurse coordinators, clinical guidelines, clinical decision support, patient engagement, and predictive algorithms to improve outcomes. The SonarMD platform is integral in this regard. Using Crohn's disease as an example, Dr. Gellad presented results showing that, compared to controls, patients receiving notifications from the SonarMD app had 57% fewer inpatient visits and 53% fewer ED visits, leading to a substantial reduction in costs (Figure 5).²⁰



Figure 5. IBD Medical Home: Benefits in Crohn's Disease

Dr. Gellad called on stakeholders to consider implementing a cirrhosis medical home. He reiterated the views of other presenters that cirrhosis is an ideal target for innovative care models because it is prevalent, well-defined, associated with high readmission rates, expensive, and deadly. Implementation and testing of a cirrhosis medical home is currently underway at Indiana University (Eric Orman, PI). In this cirrhosis medical home, an interdisciplinary clinical team will provide personalized care, including patientcentered care protocols, a mobile office, care coordination support software, and dynamic feedback measures. The care coordinator will conduct a comprehensive consultation within 72 hours of hospital discharge and meet with patients every two weeks to revisit the care plan.

Potential Opportunities to Improve CLD Outcomes

The following opportunities were discussed during the 2022 coalition meeting and are targeted for key CLD stakeholders as they work to improve outcomes for patients with chronic liver disease:

- Adapting guidelines for consistency across providers
- Ensuring patients receive high-touch care for appropriate management
- Collaborating with providers throughout the entire care continuum to address the total patient



- Utilizing electronic alert systems to increase early identification of at-risk patients
- Collaborate with payers to ensure timely access to appropriate and necessary therapies

Adapting Guidelines for Consistency Across Providers

While national treatment guidelines exist, such as the American Association for the Study of Liver Diseases' (AASLD) practice guidelines, less than half (49%) of surveyed providers utilize them in their management of CLD. Many providers are unaware of national guidelines; less than half of the respondents believed that aligning treatment with national guidelines is extremely/very important. There is also a significant implementation gap between the knowledge gained from clinical trials that are put into guidelines versus how clinicians practice. As Sammy Saab, MD, pointed out, "who (non-liver specialist providers) has time to read the guidelines, understand them, and implement them? It's unrealistic."

Variances in care across CLD providers can mean that patients fail to receive the appropriate treatments. This fragmentation occurs in both the in- and outpatient settings as well as among primary care providers and hepatologists/ gastroenterologists, and has been shown to lead to an increase in readmissions.

Patients experience their own barriers as well; individuals with cirrhosis may be managing other chronic conditions and, consequently, seeing other providers, making it challenging to keep track of prescriptions, appointments, and treatments.

Potential Opportunities: There are multiple opportunities to improve guideline adherence across all relevant providers and payers. These include but are not limited to the following:

- Provide point of care guidance when managing specific conditions
- Develop an AASLD abbreviated management guideline document prioritized by impact and feasibility for key liver disease states for payers that includes the cost/benefit implications within the major management algorithm recommendations

Ensuring Patients Receive High-Touch Care for Appropriate Management

Throughout the coalition meeting, advisors stressed the importance of increased high-touch care for patients. With affordability concerns, patients may avoid needed treatments and appointments, or avoid picking up prescriptions altogether. Some clinicians have found that patients become quickly inundated with information during their appointment

and may forget key treatment instructions soon after leaving. This puts patients at-risk for hospital readmissions and increased associated costs, further burdening the overall healthcare system. Jeff Dunn, PharmD, MBA clarified that, "it's getting to the point where it all falls down to the patient and we need to do something different, otherwise patients will not have the resources to manage their care."

More encounters with patients between advanced practice providers (APPs), registered nurses (RNs), dietitians, and social workers may result in improved long-term outcomes, but may initially incur higher costs. In the morning session, "Chronic Liver Disease and the Burden on Community Practice," Dr. Timothy Ritter described the "NASH Home,' a high-touch care model that his organization introduced. In this model, all patients with suspected NASH receive a Fi-broScan and a FIB-4 index test to confirm diagnosis and stage the severity of the liver disease. Patients with low-risk characteristics are referred to a dietitian for weight loss support, while high-risk patients receive further evaluation. Part of the evaluation may include a liver biopsy or an MR elastography and liver multiscan. Patients with advanced fibrosis are offered entry into the NASH Home, which adds multiple touchpoints to ensure medication adherence, addresses mental health issues, provides health maintenance, and offers dietitians for weight loss, among other touchpoints.

While viewed as a best practice, advisors pointed out that payer reimbursement can often be a barrier to these types of innovative models. The NASH Home model, however, bills care under chronic care management codes, potentially mitigating these concerns. To garner successful outcomes across CLDs, implementing a high-touch care team like the NASH Home model, but tailored to the specific CLD patient types, may drive better management across the care team continuum.

Potential Opportunities: To ensure patients receive hightouch care, key stakeholders may consider a surround sound approach, which could include the following:

- Add patient and/or technology navigators, (i.e. specially trained medical assistants) specific to liver disease who could bridge the gaps in patient care and communication
- Involve all members of a patient's care team via EMR alerts, email, and/or letters to guarantee appropriate tests and treatments are ordered
- Introduce NASH Home type models in other key organizations as best practice models to encourage consistent care to identify, treat, and manage pertinent CLDs



Collaborating with Providers Throughout the Entire Care Continuum to Address the Whole Patient

In tandem with high-touch care is the collaboration of all relevant providers to address the total patient. This includes involving the expertise of a specialty pharmacy department, which has traditionally been left out of the conversation, according to Dan Kus, RPh "Most people don't think about pharmacists. My vision going forward is for specialty pharmacists to be a part of the care team." Given their experience, specialty pharmacists can contribute to care path development and integrate it into an organization's EMR.

Even with a collaborative, multidisciplinary team, there are barriers to providing consistent care. Asymptomatic patients present an additional challenge for effective, multidisciplinary care. Physicians have noticed that it is difficult to engage patients, who are often decompensated by the time they begin to show symptoms. In addition, patient benefits may change from year to year, which creates disruption with a key stakeholder—the payer. Therefore, it is essential to maintain ongoing, consistent liver health-related communication with a patient's providers and other stakeholders in their care team.

Potential Opportunities: Opportunities to increase collaboration within the entire multidisciplinary care team may include the following:

- Develop a collaborative communication solution (IT) that includes desired outcomes for all participating stakeholders, including healthcare providers and managed care organizations as well as patient/health plan members
 - Identify existing elements of success with positive health economic outcomes to guide development
- Initial collaboration could be between an engaged payer, health system, and employer to develop a pilot program
 - This may also more evenly distribute upfront costs between a few stakeholders
- Consider pharmaceutical manufacturer clinical and financial resources as an additional source of insight and support in designing a CLD initiative

Utilizing Electronic Alert Systems to Increase Early Identification of At-Risk Patients

EMR embedded alerts have been utilized across health systems with clinical workflows and clinical decision support functionality. According to Ralph Riello III, PharmD, BCPS, "the EMR is the only 'provider' in the health system that sees every patient. Using that mentality, we've successfully

deployed alerts to nudge providers to reflect best practices for undertreated diseases." For example, providers can be reminded to order guideline-recommended medications and screen or test for underrecognized conditions among eligible patients. There is additional advantage to utilizing alerts that target members of the care team in the outpatient setting, rather than add to the multitude of alerts providers already encounter in the hospital.

Clinicians do not have the capacity to monitor and respond to every clinical alert. Any initiative would need to be implemented without adding to clinician workload. For example, to properly diagnose hepatic encephalopathy, clinicians must first appropriately screen for at-risk patients and therefore may be best-suited role to respond to an alert. It is therefore crucial to strike a balance between the low-value alerts that unnecessarily burden clinicians and the high-value alerts that can accurately identify and treat patients at risk.

Another drawback is EMR interoperability challenges, which can make data transfers between organizations nearly impossible. A patient with CLD likely has a primary care doctor, a hepatologist and/or gastroenterologist, a specialty pharmacist, RNs and/or a nurse navigator, a social worker, a mental health provider, and a dietitian, among various other advisors. If the entire multidisciplinary care team practices under the same health system, then EMR embedded alerts are streamlined. However, this is usually not the case, as patients may see a variety of providers across multiple practices.

Appropriately implemented alerts across diverse systems that can target the correct multidisciplinary team member and notify others in the care team could lead to improved, coordinated care, regardless of whether patients are admitted, transferred, or discharged to different facilities.

Potential Opportunities: To ensure EMR alerts target the right provider at the right time, consider the following opportunity:

 Consider a best practice advisory system that is customizable for each care team member and that is more guideline/data driven in its utility to allow better adherence to the appropriate guidelines and thus lead to a decrease in unnecessary future clinical events and costs

Conclusion

The CLDF has an opportunity to partner with key, engaged industry stakeholders to develop a pilot program with supporting resources based on any number of the above unmet needs. For example, an integrated delivery network



(IDN) that seeks to improve its cirrhosis outcomes and decrease readmissions would be an excellent partner for collaboration with the CLDF to further develop these educational tools and targeted initiatives. IDNs that adopt a surround sound, multidisciplinary, high-touch approach that is consistent across all sites of care can likely expect improved outcomes. In addition, payers have been identified as critical stakeholders to collaborate with in order to develop the tools and resources needed to achieve the Triple Aim of improving patient care coverage and access, driving quality and efficiency, and managing costs.

Achieving the ultimate goal of better outcomes in CLD can improve the utilization of healthcare resources across this complex patient base. The CLDF continues discussions with stakeholders to drive this goal. This paper is a beginning and does not represent an exhaustive list of all possible initiatives within the CLD management space. Advisors noted that implementing more than one approach may be necessary to meet providers and payers where they currently are in their processes to insure progress at all levels. There may be value in first proving the worth of the coalition by implementing a smaller-scale initiative or tangible resource, then involving more stakeholders for a longer-term, more broad-based program initiative. Regardless of the initiative decided, advisors resoundingly agreed that the CLDF Health Outcomes Coalition, and groups like it, are necessary to devise innovative, practical solutions to better patient care, outcomes, and cost efficiencies in CLD. There is more to come with our collective goal to better manage CLD across all stakeholders.

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Appendix A: Advisor Backgrounds

Jeff Dunn: Prior to CBG, Jeff served as the Head of Clinical Pharmacy at Haven, the Amazon, Berkshire Hathaway, JPMorgan Chase healthcare venture. He also brings extensive PBM experience through his tenure at Magellan Rx as their Vice President of Clinical Strategy and Programs and Industry Relations. Throughout his experience, Jeff has managed pharmacy and formulary programs, been part of pharmacy and therapeutics committees, and engaged in contracting and rebates for traditional and specialty drugs.

Christopher Goff: Chris is the CEO and general counsel of Employers Health Purchasing, a position he has held for over 25 years. He brings extensive experience managing over \$2.2 billion in annual drug spending as a PBM contract holder and continuously consults with employers in vendor selection and benefit design.

Eduardo Kneler: Eduardo has contributed to the adjudication of treatment requests for organ transplants and surgical and radiological procedures and has served as a medical consultant for California's Department of Health Care Services.

Dan Kus: Dan has served as the Vice President, Ambulatory Pharmacy Services at Henry Ford Health System for over 20 years. In this role, he is responsible for 30 ambulatory pharmacies and one national specialty and mail order pharmacy. He's assisted with pharmaceutical contracting for 700,000 HMO members, the implementation of utilization management initiatives, and oversight of Henry Ford's 30 medical clinics and six hospitals within the 340B program.

Myla Maloney: Prior to her position at Premier, Myla worked in various positions throughout her 15-year tenure at Merck, notably as a Market Leader and Integrated Delivery Systems Account Leader.

Vishal Patel: Vishal has been a practicing hospitalist for over 19 years and currently works at St. Joseph Health Medical Group.

Ralph Riello III: Ralph is a board-certified clinical pharmacy specialist with expertise in cardiovascular medicine, critical care, and clinical research. He has extensive expertise in clinical decision support technology, cost containment, quality improvement, and formulary management experience.

Michael Thompson: Michael is a seasoned executive and trusted advisor with a 35-year track record of thought leadership, diverse experiences, distinguished collaboration, and sustained success in both for-profit and not-for-profit initiatives and roles. Currently, Michael is the President and CEO of the National Alliance of Healthcare Purchaser Coalitions. In this role, he has led the development of a value-based agenda for the organization, reinvigorated national stakeholder engagement in the purchaser agenda, and established initiatives related to mental health, opioids, oncology, and specialty.

