Pain Management Best Practices Inter-Agency Task Force Meeting Summary
June 26, 2019, 5:00 p.m. – 6:30 p.m.

Welcome, Meeting Purpose and Objectives: 5:00 p.m. – 5:05 p.m.

Shari Ling, MD, Deputy Chief Medical Officer, Centers for Medicare and Medicaid Services (CMS), thanked participants for joining and welcomed Task Force members and shared the purpose of the day's meeting:

- As part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act, Sec. 6032, CMS is required to develop an opioid and substance abuse disorder action plan that applies to Medicare and Medicaid coverage and policies.
- The purpose of today's meeting is to gather feedback on identified areas of action, which will then be taken into consideration in the development and implementation of the action plan.
- This conversation also lays the foundation for a future state of health care that will be a person-centered approach and can better deliver meaningful outcomes for all the people that CMS serves, including individuals with painful conditions and symptoms.

Roll Call and Call to Order: 5:05 p.m. – 5:15 p.m.

Alicia Richmond Scott, MSW, Designated Federal Officer, US Department of Health and Human Services (HHS), described her role as liaison between the Task Force and HHS, and her responsibility to ensure that all Task Force operations comply with the provisions set forth in the Federal Advisory Committee Act and that no ethical statutes or regulations are violated.

- Ms. Scott noted limited time in the meeting for oral public comments and encouraged the public to provide written comments in regulations.gov., open until 11:59 p.m. on 6/26/2019.

The following Task Force members were in attendance:

- Vanila Singh, MD, Task Force Chair, Chief Medical Officer (CMO) in the Office of the Assistant Secretary for Health (OASH), US Department of Health and Human Services (HHS)
- Sondra M. Adkinson, PharmD
- Commander René Campos, MBA
- Jianguo Cheng, MD, PhD
- Rollin M. Gallagher, MD
- Halena M. Gazelka, MD
- Nicholas Hagemeier, PharmD, PhD
- Sharon Hertz, MD

- Jan Losby, Ph.D.
- Michael J. Lynch, MD
- John McGraw, MD
- Mary W. Meagher, PhD
- John V. Prunskis, MD
- Molly Rutherford, MD
- Friedhelm Sandbrink, MD
- Bruce A. Schoneboom, PhD
- Cecelia Spitznas, PhD
- Cindy Steinberg
- Harold K. Tu, MD, DMD
- Sherif Zaafran, MD

Facilitated Discussion with Task Force Members: 5:15 p.m. – 6:25 p.m.

Vanila Singh, MD, Task Force Chair, Chief Medical Officer (CMO) in the Office of the Assistant Secretary for Health (OASH), US Department of Health and Human Services (HHS)

- Emphasized CMS's commitment to addressing substance use disorder and improving outcomes for those in that population as well as those with acute and chronic pain, and where the intersection of both meet.
- Noted that the day's discussion would center around six questions that were provided by CMS as required by the SUPPORT Act (and a 7th question, if time allows). For each question, Dr. Singh will read the question, note the relevant recommendations from the Task Force final report, and then the Task Force will discuss for 5 to 10 minutes.
- Noted that the last question of the six questions will pertain to the top three recommendations of highest impact from the Task Force final report.

Question 1

Please identify any Medicare payment and coverage policies related to therapies that manage acute and chronic pain and minimize risk of opioid misuse and abuse. Have these payments and coverage policies resulted in incentive or disincentive that have contributed to the nation's opioid crisis? If so, how?

Relevant Recommendations from Task Force Final Report

- Page 56, recommendation 1A – "Encourage CMS and private payers to provide sufficient compensation for time and payment for services to implement the various screening measures such as extensive history taking, review of medical records, PDMP query, urine toxicology when appropriate, and other labs when clinically indicated. These are vital aspects of risk assessment and stratification for patients on opioids and other medications."
- Page 56, recommendation 1B – "Consider referral to pain, mental health and other specialists, including addiction medicine-trained physicians when high-risk patients are identified."
- Page 29, recommendation 4B – "Encourage CMS and private payers to provide coverage and reimbursement for buprenorphine treatment, both for OUD and for chronic pain when both are present in particular. Encourage primary use of buprenorphine rather than use only after failure of standard of mu-agonist opioids such as hydrocodone or fentanyl, if clinically indicated."
- Page 37, recommendation 2A – "Encourage CMS and private payers to provide consistent and timely insurance coverage for evidence-informed interventional procedures early in the course of treatment when clinically appropriate. These procedures can be paired with medication and other therapies to improve function and quality of living and ADL."
- Page 37, recommendation 2B – "CMS and other payers must restore reimbursement to non-hospital sites of service to improve access and lower the cost of procedures."
- Page 28, recommendation 2E – "CMS and private payers should provide reimbursement that aligns with the medication guidelines the Task Force has described. Private payers and CMS should provide more flexibility in designing reimbursement models."
- Page 28, recommendation 2F – "PBMs or pharmacy benefit managers and payers should be more transparent about non-opioid pharmacologic and non-pharmacologic options in their formulary, and the Task Force encourages state and federal regulators to review payer and PBM formularies to ensure that non-opioid options are on low-cost tiers."

Discussion

Dr. Michael Lynch

- Noted that the recommendations specific to this question are important to allow patients to access non-opioid medications, such as buprenorphine, for which there are often coverage issues.
- Emphasized that further reimbursement or equal tier reimbursement of buprenorphine for pain management and non-opioid management is critical for patients who don't have all of the

options available to them even when recommended by a physician and have to come back after refusal of authorization for alternative treatment.

Dr. Molly Rutherford

- Raised the issue of Medicaid prior authorizations for buprenorphine and the obstacle it creates for individuals receiving treatment for substance use disorder.
- Recommended that CMS consider increasing Medicaid reimbursements. Noted that although Kentucky has expanded Medicaid, the access issue persists because so many physicians cannot afford to contract with Medicaid.
- Requested clarity as to whether it is legal for direct primary care providers to opt out of Medicaid in the same way they may opt out of Medicare. This would allow direct primary care providers to take on Medicaid patients.

Dr. Sharon Hertz

- Noted that prescribers have indicated they would like to have access to combination products, including naloxone combination products, to manage patients who do not have a formal substance use disorder diagnosis but who have pain plus additional risk factors, or where clinical judgement indicates the combination product would be potentially useful. In the absence of having a formal substance use disorder diagnosis, prescribers have difficulty accessing those products.

Dr. Rollin Gallagher

- Brought up the issue of compensation for evaluating the complexity of patients with chronic pain. Primary care should have the time and resources to evaluate patients for SUD risk factors and provide appropriate treatment or referral.
- Noted that if a provider has only 15-30 minutes, it is not feasible to complete the kind of evaluation and risk assessment that are necessary and to develop an appropriate treatment plan.

Question 2

Please identify any payment and service delivery models, including value-based models, that may encourage the use of therapies that manage acute and chronic pain and treat and minimize the risk of opioid misuse and abuse that could be tested by CMS and Medicare/Medicaid and/or the Children's Health Insurance Program through CMS' Center for Medicare and Medicaid Innovation or by other federal agencies.

Relevant Recommendations from Task Force Final Report

- Page 22 recommendation 1A – "Use procedure-specific, multimodal regimens and therapies when indicated in the perioperative period, including various non-opioid medications, ultrasound-guided nerve blocks, analgesia techniques – examples of lidocaine, ketamine infusions – and psychological and integrative therapies to mitigate opioid exposure." *(this is in reference to an acute period of pain)*
- Page 22, recommendation 1B – "Use multidisciplinary and multimodal approaches for perioperative pain control in selected patients at higher risk for opioid use disorder (e.g., joint camps where total joint and hips are put in as certain programs, Enhanced Recovery After Surgery, Perioperative Surgical Home). Key components for optimal pre-habilitation may include preoperative physical therapy, nutrition and psychology screening and monitoring; preoperative and postoperative consultation and planning for managing pain of moderate to severe complexity; preventive analgesia with preemptive analgesic non-opioid medications; and regional anesthesia techniques, such as continuous catheter-based local anesthetic infusion." *(this is a perioperative acute pain recommendation)*
- Page 22, recommendation 1C – "Encourage CMS and private payers to develop appropriate reimbursement policies to allow for a multimodal approach to acute pain in the perioperative setting."
- Page 56, recommendation 1A – "Encourage CMS and private payers to provide sufficient compensation for time and payment for services to implement the various screening measures (e.g., extensive history taking, review of medical records, patient consultation advisement, PDMP query, labs as indicated). These are vital aspects of risk stratification and assessment for patients on opioids and other medications."
- Page 61, recommendation 2C – "CMS and private payers should recognize that the time spent educating and managing patients' expectations is cost-effective and provides a significant value that reduces the length of hospital stays and improves patients' postoperative pain management as well as other situations, allowing for faster recovery through earlier interventions, including physical therapy and mobility, that decreases the risk for postoperative and other situational complications as CMS and other payers should compensate according to physician-patient time spent."
- Page 65, recommendation 1B – "CMS and private payers should investigate and implement innovative payment models that recognize and reimburse holistic, integrated, multimodal, multidisciplinary pain, including behavioral health."

Discussion

Dr. John McGraw

- Shared that, as medical director of the largest group in Tennessee, they are frequently asked about pain-reliving or elective surgeries with patients who have substance use disorders – should they proceed with the surgery, and if so, how will they control that patient's pain afterwards?
- Dr. McGraw encourages his surgeons to reach out to the chronic pain physician clinic and to coordinate postoperative pain to the best of their ability but notes that this process is time-consuming and sometimes an additional mental health evaluation is needed.

Ms. Steinberg

- Asked that CMS look into patient education and support groups, self-management programs, and certified exercise programs (e.g., yoga, tai chi) as innovative ways to help patients manage their own conditions.
- Another innovative model (currently being attempted in Massachusetts) is providing no-cost consultations with specially trained teams of pain management experts to primary care providers. The goal is to encourage PCPs to keep their pain patients rather than discharging them because they are complex.

Dr. Vanila Singh

- In response to Ms. Steinberg's comment, noted another relevant recommendation: page 60, recommendation 1B – "Explore and test innovative methods of delivering patient education and support for patients with acute or chronic pain using technology, particularly in rural areas that have limited access to multimodal treatment."

Dr. Bruce Schoneboom

- Expressed support for models of anesthesia delivery that decrease patients' use of and exposure to opioids but noted that requires having reimbursement models in place to incentivize providers to use enhanced recovery services.
- Furthermore, need to ensure that reimbursement models do not discriminate based on type of provider, as in some areas the only anesthesia provider may be a nurse anesthetist.

Dr. Molly Rutherford

- Suggested using HSAs or FSAs to help Medicare patients pay for enhanced recovery or support services.
- Cautioned against adding complications for direct care and front-line physicians. Noted that face-to-face time is not valued as much as, for example, a year-end drug screen.

Question 3

How can CMS improve access to therapies in Medicare and Medicaid that manage acute and chronic pain and minimize the risk of opioid misuse and abuse, including in rural or medically underserved communities? What key special populations should CMS target for improved access?

Relevant Recommendations from Task Force Final Report

- Page 65, recommendation 1A – "Reimburse complex opioid and non-opioid management consistent with the time and resources required for patient education, safe evaluation, risk assessment, re-evaluation and integration of alternative, non-opioid modalities."
- Page 65, recommendation 1B – "CMS and private payers should investigate and implement innovative payment models that recognize and reimburse holistic, integrated, multimodal pain management, including behavioral health."
- Page 65, recommendation 3A – "CMS and other payers should align their reimbursement guidelines for non-opioid pharmacologic therapies with current clinical practice guidelines."
- Page 65, recommendation 4B – "Payers should reimburse for pain management in a manner that facilitates access in underserved locations through telehealth or other technology-assisted delivery methods." (To expand on that, many of those are online support groups, e-mobile apps that are validated.)
- Referring to the special population section of the Task Force report, pages 42 to 51, the special populations that deserve key targeting for CMS amongst others include the pediatric use population, older adults, patients with cancer-related pain and patients in palliative care, women, pregnancy, chronic relapsing pain conditions. One example is patients with sickle cell disease who have limited treatment options for pain and face health disparities.
- Another special population noted in the report are the military active duty, reserve service members, and veterans, many of whom have PTSD, anxiety and other mood disorders, and special pain issues including phantom limb pain and spinal cord injury, and are at risk for potential opioid use disorder or substance use disorder.

Discussion

Dr. Nicholas Hagemeier

- Suggested that CMS consider recognizing pharmacists as providers since they often play a key role in facilitating pain care in primary care clinics. This would help in terms of reimbursement and allowing patients access to therapies.

Dr. Cecilia Spitznas

- Recommended that CMS review all potential opioid alternatives and consider if their policies are consistent with the President's priorities for preventing opioid misuse. Provided the example that reimbursement for injectable acetaminophen is not allowed because oral acetaminophen is very inexpensive, but it could be a replacement for fentanyl or morphine.
- Noted that bupivacaine liposome bundling may be limiting its uptake in certain settings, like the hospital setting, and limiting access to opioid alternatives.
- Recommended that CMS consider offering access to disposal technologies along with prescriptions, especially for rural and underserved populations.

Dr. Sharon Hertz

- Suggested CMS use caution when considering acetaminophen as a replacement for an opioid since there is no supporting data.
- Noted that since liposomal bupivacaine has never been shown to be superior to IR regular bupivacaine, there is little justification for liposomal bupivacaine from a cost perspective.

Question 4

How can CMS improve access to therapies, identify problematic payment and coverage policies, identify payment and service delivery models and increase access to medical devices, mobile apps, telementoring and telemedicine in Medicare and Medicaid that treats beneficiaries with both opioid use disorder and acute or chronic pain?

Relevant Recommendations from Task Force Final Report

- Page 65, recommendation 3A – "CMS and other payers should align their reimbursement guidelines for non-opioid pharmacologic therapies with current clinical practice guidelines."
- Page 40, recommendation 1C – "Improve reimbursement policies for integrated, multidisciplinary, multimodal treatment approaches that include psychological and behavioral health interventions through traditional and nontraditional delivery methods such in-person, telehealth, Internet self-management, mobile apps, group sessions."

- Page 60, recommendation 1B – "Explore and test innovative methods of delivering patient education and support for patients with acute or chronic pain using technology, particularly in rural areas that have limited access to multimodal treatment. Examples of means to provide patient access in such situations include telemedicine online support groups, networks of in-person support groups with training and guidance from leaders and applications easily accessible on mobile devices."
- Page 39, recommendation 1A – "Increase access to evidence-based psychological interventions, including the full range of treatment deliveries with hub-and-spoke models, telehealth, Internet self-management and mobile applications."
- Page 62, recommendation 1C – "Explore intensive continuing pain education for primary care physicians, including telehealth, telementoring models and the Project ECHO model, as a means of providing pain education for primary care providers by pain specialists. Consider the State Targeted Response Technical Assistance Consortium model for pain training as it currently exists."
- Page 37, recommendation 2A – "Encourage CMS and private payers to provide consistent and timely insurance coverage for evidence-informed interventional procedures including medical devices such as that – which is in neuromodulation techniques early in the course of treatment when clinically appropriate. These procedures can be paired with medication and other therapies to improve function, quality of life and ADL."

Discussion

Dr. John Prunskis

- Noted that CMS has inconsistent policies, where a minimally invasive (percutaneous) procedure to place a low-risk medical device has more pre-authorization requirements than other procedures with similar or less risk or invasiveness. The example provided was a neuromodulation/spinal cord stimulation trial, for which CMS and other payers require pre-approval by a behavioral medicine specialist; in contrast, spinal fusion surgery does not require a behavioral health assessment.

Dr. Bruce Schoneboom

- Reiterated the Task Force recommendation that a national coverage determination may be helpful to minimize variation of care. The Task Force noted that local coverage determinations cause variation of care across the United States and recommended standardizing care at the national level within certain problematic payment policy areas.

Dr. John McGraw

- Agreed with Dr. Schoneboom's comment and noted that his region, where the Medicare Administrative Contractor is Palmetto, there is significant variance from some of the other local coverage determinants and it is difficult to know what the correct model is coming out of CMS.

Question 5

How can CMS improve Medicare and Medicaid beneficiaries' access to medical devices that are non-opioid-based treatments for pain approved by the Department of Health and Human Services, FDA for the management of acute and chronic pain and for preventing overdoses of controlled substances such as prescription opioids? What specific barriers exist in Medicare and Medicaid payment and coverage policies for – to beneficiaries to access such devices?

Relevant Recommendations from Task Force Final Report

- Page 37, recommendation 2A – "Encourage CMS and private payers to provide consistent and timely insurance coverage for evidence-informed interventional procedures including medical devices such as that – which is in neuromodulation techniques early in the course of treatment when clinically appropriate. These procedures can be paired with medication and other therapies to improve function, quality of life and ADL."
- Page 37, recommendation 2B – "CMS and other payers must restore reimbursement to the non-hospital sites of service to improve access and lower the cost of interventional procedures in general."

Discussion

- No additional comments (Dr. Singh noted that this was largely covered in previous discussions.).

Question 6

What are the recommendations of highest impact from the final Task Force report that can improve health outcomes for individuals with acute and/or chronic pain or individuals with chronic pain and opioid use disorder?

Relevant Recommendations from Task Force Final Report (in no specific order)

- Page 65, recommendation 4A – "Payers should reimburse pain management using a chronic disease management model. CMS and private payers should reimburse for integrative, multidisciplinary pain care by using a chronic disease management model like that currently used to reimburse for cardiac rehabilitation and diabetes chronic care management programs. In addition, reimburse care team leaders for time spent coordinating patient care. A CPT code should be developed for pain care coordination as well as team and group conferences that enable multidisciplinary care and discussion."

- Page 65, recommendation 1A – "Reimburse complex opioid and non-opioid management for chronic pain and acute pain consistent with the required time and resources for patient education, safe evaluation, risk assessment, with periodic re-evaluation and integration of alternative, non-opioid modalities."
    - Dr. Singh noted that goes to pharmacologic and non-pharmacologic – devices, interventions, behavioral health, restorative therapies, complementary and integrated health are included in that.
- Page 22, recommendation 1C – "Encourage CMS and private payers to develop appropriate reimbursement policies to allow for a multimodal approach to acute pain in the perioperative setting and the peri-injury setting, including preoperative consultation to determine a multimodal plan for the perioperative setting."
    - Dr. Singh emphasized that in the peri-injury setting such as the hip fracture setting, interventions such as femoral nerve blocks, which minimize the need for opioids, are often not well reimbursed.
- Page 56, recommendation 1A – "Encourage CMS and private payers to provide sufficient compensation for time and payment for services to implement the various screening measures – for example, extensive history taking, review of medical records, PDMP query."
    - Dr. Singh noted these data are required now by many states when initiating opioids or other controlled substances – urine and lab screens. She also emphasized Dr. Rutherford's comment about face-to-face time when taking patient histories and added that what goes with this recommendation is the timely payment and authorization required for those other modalities.
- Page 65, recommendation 3A – "CMS and other payers should align their reimbursement guidelines for non-opioid pharmacologic therapies with current clinical practice guidelines."
- Page 22, recommendation 1A – "Use procedure-specific, multimodal regimens and therapies when indicated in the perioperative period, including various non-opioid medications, ultrasound-guided nerve blocks, analgesia techniques, such as lidocaine or ketamine infusions, and psychological and integrative therapies to mitigate opioid exposure that isn't necessary."
    - Dr. Singh stated that it is dependent on the patient, their comorbidities, the surgery they are having.
- Page 37, recommendation 2B – "CMS and other payers must restore reimbursement to the non-hospital sites of service."
- Page 62, recommendation 1C – "Explore intensive continuing pain education for primary care clinicians, including telehealth, telementoring."

    - Dr. Singh noted this includes front-line clinicians having timely access to pain specialists' consultation via telementoring or other mental health and addiction specialists and the Project ECHO model as a means of providing pain education.
- Page 65, recommendation 4B – "Payers should reimburse for pain management in a manner that facilitates access in underserved areas through telehealth or other technology-assisted delivery methods."

Discussion

Dr. Sherif Zaafran

- Expressed that the most important point is that CMS and Medicare recognize time and reimbursement – that these various procedures and alternative mechanisms need to be compensated for. The commercial side will follow CMS's lead.

Dr. Vanila Singh

- Agreed with Dr. Zaafran that providers across the spectrum feel there is simply not enough time to evaluate, properly diagnose, and develop a treatment plan that would help individuals retain their work, quality of life and ADL – indicators of improved functionality.

Dr. Mary Meagher

- Stated that for behavioral health interventions to become available and accessible to clients and patients, and for mental health providers to pursue pain psychology, the incentive and payment structures must change.

Dr. Vanila Singh

- Noted that Dr. Meagher's point is represented on page 39, recommendation 1A and page 40, recommendation 1C – "improving reimbursement policies for integrated multimodal, multidisciplinary care including that of psychological and behavioral health."

Dr. John Prunskis

- Supported CMS's paperwork burden reduction efforts and encouraged CMS to explore ways to reduce electronic health record and data entry burden so that providers can spend significant meaningful time helping to diagnose and treat a patient's painful condition.

Dr. Vanila Singh

- Emphasized that clinical administrative burden is a significant pain point for the entire health care team – physicians, physician assistants, nurse practitioners, social workers, etc.

Dr. Jan Losby

- Restated a point included in recommendation 4A – the importance of looking at reimbursement for care team leaders or care coordinators to support multidisciplinary care and potentially address the amount of time that primary care physicians have in accessing the conversations that they have with patients.

Dr. Vanila Singh

- Agreed with Dr. Losby's point and added that the return on investment of getting it right the first time through multidisciplinary care allows for better prevention of hospitalizations and recurrent ER visits.
- Reiterated that the investment for improved reimbursement for face-to-face time and non-pharmacologic behavioral health services could be offset by reductions in clinical administrative burden, which can improve productivity. Those gains can be directed towards achieving better patient outcomes.

Dr. Molly Rutherford

- Urged CMS to value primary care – when primary care is valued and emphasized, it pays off long-term.
- Noted that several people who have written about the opioid epidemic have pointed to the fact that primary care providers only get seven minutes with patients as a cause of overprescribing.

Dr. Rollin Gallagher

- Recommended that CMS apply evidence-based integrated team models and "older" bundled payment structures from previous decades to treat complex chronic pain patients.

Dr. Vanila Singh

- Brought forward two additional items:
    - Page 63 of the Task Force report mentions CMS and the SUPPORT Act. The Task Force expressed concern about the definition of an "outlier prescriber" and urged CMS to avoid arbitrary limitations without accounting for provider expertise and the patient demographic - "Patient care should be based primarily on the clinical context and the patient-clinician interaction. Opioid stewardship programs can provide a holistic,

efficient, comprehensive, multidisciplinary approach to address safer opioid prescribing within the health system thus empowering cross-disciplinary collaboration and inclusion with the development of measures to guide implementation and successful efforts. Quality measures should include function, quality of life and activities of daily living" as a guide to safe opioid stewardship. "The SUPPORT Act requires CMS to convene a technical expert panel make recommendations regarding quality measure for opioids, identify outlier prescribers and furnish technical support regarding proper prescribing practices and implement minimal standards for states' drug utilization review programs regarding opioid prescribing, including safety (added to refills) and the daily dosage policies. We know it is essential to ensure that careful consideration of clinical context is always considered."

- Invited Task Force members who had not yet spoken to share any thoughts or recommendations.

Dr. Friedhelm Sandbrink

- Emphasized the importance of giving providers the ability to assess and treat patients from an individual standpoint and meet their unique needs. Clinical guidelines are important, but they are not policies or mandates. Expressed concern, for instance, about patients being cut off opioid medication because a provider feels they have reached their own quota for the day or week.
- Noted that for some patients, reductions, even if they are indicated, may take a long time to implement. It is important that providers have the assurance that they can provide treatment that meets individual patient needs.

Dr. John Prunskis

- As discussed in the report, cautioned against stigmatizing the patient who truly needs opioids or the doctor who ethically/in good faith is prescribing opioids and should not be subject to overzealous state regulatory or federal office prosecution or oversight.
- Noted that press releases about doctors who are under review for opioid prescribing practices can be misleading.
- Suggested that rather than going after the license of providers who are operating in good faith and prohibiting them from prescribing controlled substances, CMS consider medical education or training as a first step.

Dr. Sherif Zaafran

- Noted that state medical boards will be looking for guidance from the Task Force report as well as how CMS plans on implementing the recommendations, and how the Task Force communicates about associated rules and regulations.
- Stressed the importance of educating regulatory agencies and policymakers on the implementation side if CMS expands reimbursement and payment mechanisms.
- Stated that the medical boards are probably in the best position to ensure that physicians can treat patients with appropriate guardrails without having the fear of regulators coming after them when they are doing the right thing. An important factor has been focusing on outcomes and functionality (as stated in the report) over arbitrary numbers like NMEs or other negative factors.

Dr. Jianguo Cheng

- Recommended that CMS have measures to safeguard patients' access to care. Stated that for many patients, the most important thing is having better access to care.

Question #7

Describe any recommendations regarding ways to lower price trends for drugs used to reverse opioid overdoses, such as naloxone.

Relevant Recommendations from Task Force Final Report

N/A

Discussion

Dr. Molly Rutherford

- Suggested that one option is to get rid of the pharmacy benefit manager (PBM) - there may currently be some legislation on this issue. There is a loophole in current law regarding PBMs and they receive kickbacks on medications.

Dr. Cecilia Spitznas

- Noted that Kaleo, maker of the disproportionately expensive autoinjector, will soon offer a generic version which should decrease the cost. Recommended that CMS keep an eye on legislation that may block that.
- Expressed that the price trend is not necessarily an accurate reflection. Recommended that CMS reimburse for the branded naloxone products that were approved for use by community or layperson users because the efficacy of the regular pre-filled syringe version with the atomizer has not been demonstrated in clinical trials.

Dr. Vanila Singh

- Noted a relevant gap included in the final report, page 31 – "Bystander/take-home naloxone distribution is associated with a cost-effective reduction in mortality; however, its optimal use is not widely understood, and it is not widely distributed."
- The Task Force recommendations for this gap included "provide naloxone co-prescription, dispensing and education for certain patients/caregivers where the patient is on chronic opioid therapy", "increase naloxone distribution program and education for first responders", "encourage FDA and other entities to research the potential risks and benefits of making naloxone available over the counter", and "education health care providers and the public on the importance of identifying individuals with a higher risk of overdose harm because of their history or findings consistent with substance abuse or use of illicit drugs that can – from opioids."
- Noted that naloxone is not effective in any other type of overdose situation, and there are reports of individuals misusing naloxone for the wrong indications.

Dr. Sondra Adkinson

- Recommended that CMS/Medicare recognize pharmacists as an important part of the health care team and reimburse them for their patient care services (the VA does this well because they don't have to worry about who pays for it). At the VA, pharmacists play a key in providing opioid overdose education and naloxone distribution to reverse accidental and unintended overdoses. Pharmacists can prescribe, dispense, educate, and search dashboards to identify those at higher risk.
- Echoed Dr. Sandbrink's comments regarding the opioid stewardship initiative.
- Noted that pharmacists carry naloxone throughout the facilities at the VA, a practice that was recognized as a best practice by the Joint Commission.

Dr. Vanila Singh

- Noted that access to naloxone is important for individuals who have stopped using opioids or are in a seemingly less risky situation, as they sometimes gain access to opioids from family/friends or the black market, fail to realize that their tolerance has changed, and then overdose accidentally.
- Concluded the discussion and thanked the Task Force members for their contributions. Noted that the Task Force brings expertise from emergency medicine, toxicology, primary care, addiction, mental health, representatives of professional organizations at the regulatory level,

individuals representing acute and chronic pain settings, inpatient and outpatient settings, and the veteran service organizations and special populations.

- Emphasized the need for payment and reimbursement for time spent with the patient, and for the screening and tools that are mandated for patients who have opioid treatment, whether it is for substance use or for chronic pain.

Wrap up and Summary of Feedback: 6:25 p.m. – 6:30 p.m.

Dr. Shari Ling

- Echoed Dr. Singh's thanks to all who joined the call and provided input.
- Summarized high-level areas of focus:
    - Explore opportunities to address the time issue and the request for face-to-face opportunities, and payment that reflects multimodal, multidisciplinary, interdisciplinary care that is well coordinated over time and space (consider for future care and payment models).
    - Align all that we do with outcomes that matter to the people we serve – function, quality of life – that which impart meaning to the care and services that are provided.
    - Start clinical episodes and provider-patient interactions by not only doing screening but also thinking about the treatment plan. Think about required key elements to include in an EHR to support that.
- Next steps:
    - Public meeting scheduled for September 20, 2019.
    - Request for Information will be released soon as part of CMS's action to fulfill 6032, the SUPPORT provision.