Risk Evaluation and Mitigation Strategies (REMS) for Opioids

Presented by: Yong jun Bae, Pharmacy Intern

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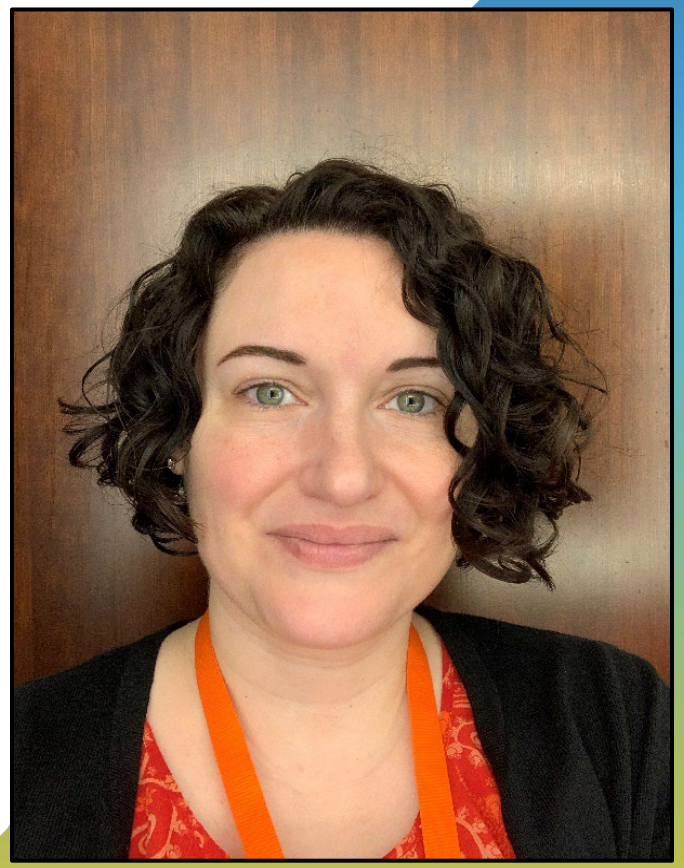
Tanya Vadala, Pharm.D.

MEDICATION SAFETY PHARMACIST

Tanya is an IPRO pharmacist with 19 years of clinical pharmacy, community pharmacy, academia, quality improvement and medication safety experience. Prior to joining IPRO, she worked at various community pharmacies and taught at the Albany College of Pharmacy and Health Sciences in Albany, N.Y. She specializes in Medication Therapy Management (MTM), medication reconciliation, opioids, immunizations and patient self-care. Her formal teaching experience includes courses in pharmacy practice and clinical experiential teaching.



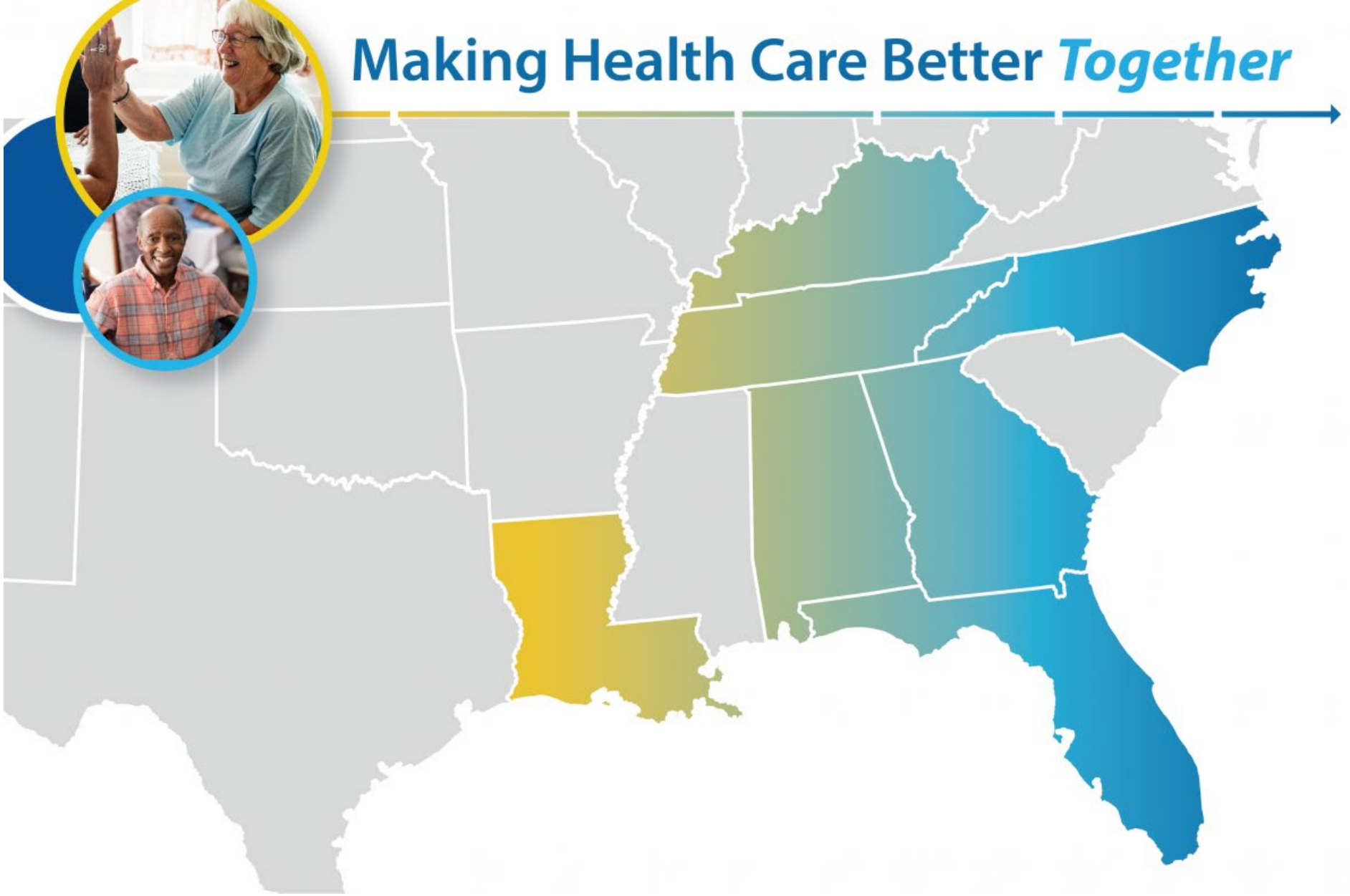
Contact: TVadala@ipro.org

Yong jun Bae, Pharmacy Intern

PHARMACY STUDENT

Yong is a PharmD/MBA in healthcare management student in his last year of pharmacy school at Albany College of Pharmacy and Health Sciences in Albany, NY. Yong has a bachelor's degree in biology from Binghamton University. He has worked at an independent community pharmacy for a year and completed rotations at a hospital and a doctor's office that specializes in addiction medicine. He plans to pursue a role as an MSL in the future.

Contact: Yongjun.bae@acphs.edu



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Objectives

- Define REMS
- Describe the role of REMS in opioids
- Examine the impact of REMS on opioid prescribing

What Are REMS?

- A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the Food and Drug Administration (FDA) can require for certain medications.
- The FDA Amendments Act of 2007 gave the FDA the authority to require a REMS from manufacturers to ensure the benefits of a drug or biological product outweigh its risks.

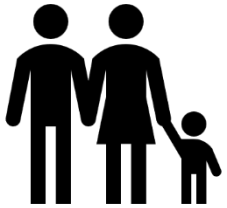
Center for Drug Evaluation and Research. (n.d.). Risk evaluation and mitigation strategies (REMS). U.S. Food and Drug Administration. Retrieved June 6, 2022, from https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems

What Are REMS?

- These medications can have serious safety concerns for patients.
- REMS are not designed to mitigate all adverse events of the medication.
- REMS focuses on preventing, monitoring and managing specific serious adverse events associated with the medications through informing, educating and reinforcing behaviors to reduce the frequency or severity of adverse events.

Center for Drug Evaluation and Research. (n.d.). Risk evaluation and mitigation strategies (REMS). U.S. Food and Drug Administration. Retrieved June 6, 2022, from https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems

Why Are REMS Important for Patients?



- REMS provides a way for patients to access to medications with serious risks that may otherwise not be available.

- Patients can receive information or counseling about a serious risk associated with a medication, actions they may need to take to mitigate a serious risk and symptoms to report to their health care provider.

Center for Drug Evaluation and Research. (n.d.). *Rems roles*. U.S. Food and Drug Administration. Retrieved June 8, 2022, from https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/roles-different-participants-rems#:~:text=Even%20if%20your%20hospital%2Fhealth,or%20to%20your%20emergency%20department.

Why Are REMS Important for Prescribers?

- Health care providers (HCPs) with prescribing privileges can ensure that medications requiring REMS due to serious risks are used safely.

- Certain REMS may have requirements for prescribers, including enrollment in the REMS, enrollment of patients, completion of training, documentation of patient counseling, patient monitoring, and documentation of compliance with certain safe use conditions.

Center for Drug Evaluation and Research. (n.d.). *Rems roles*. U.S. Food and Drug Administration. Retrieved June 8, 2022, from https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/roles-different-participants-rems#:~:text=Even%20if%20your%20hospital%2Fhealth,or%20to%20your%20emergency%20department.

Why Are REMS Important for Dispensers?

- Pharmacists and other dispensers can play a role in ensuring medications with serious risks requiring a REMS are dispensed and used safely by patients.

- Certain REMS may have requirements for dispensers, including certification to dispense the medication, training by an authorized representative of the pharmacy, and training of staff to ensure compliance with the requirements of the REMS.

Center for Drug Evaluation and Research. (n.d.). *Rems roles*. U.S. Food and Drug Administration. Retrieved June 8, 2022, from https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/roles-different-participants-rems#:~:text=Even%20if%20your%20hospital%2Fhealth,or%20to%20your%20emergency%20department.

The Opioid Analgesic REMS

- On July 9, 2012, the FDA approved the extended-release and long-acting opioid analgesic risk evaluation and mitigation strategy (ER/LA REMS).
- On September 18, 2018, the FDA modified the opioid analgesic REMS to include immediate-release (IR) opioids.
- “The opioid analgesic REMS is intended to support other national efforts underway to address the misuse and abuse of prescription opioid analgesics.”

Center for Drug Evaluation and Research. (n.d.). Risk evaluation and mitigation strategy (REMS) for opioid analgesics. U.S. Food and Drug Administration. Retrieved June 7, 2022, from https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems

The Opioid Analgesic REMS

- The opioid analgesic REMS requires all opioid analgesic companies to provide the following:
    - Education for HCPs who participate in the treatment and monitoring of pain. This includes prescribers and other HCPs who treat and monitor patients receiving opioid analgesics, including pharmacists and nurses. This education is to be offered through continuing education (CE) activities.
    - Information for HCPs to utilize when counseling patients about the risks of extended-release, long-acting and immediate-release opioid analgesic use.

Center for Drug Evaluation and Research. (n.d.). Risk evaluation and mitigation strategy (REMS) for opioid analgesics. U.S. Food and Drug Administration. Retrieved June 7, 2022, from https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems

Why Is HCP Education Important?

- HCP education on the fundamentals of acute and chronic pain management and the risks associated with opioid use can ensure that patients get appropriate counseling for their medications and use them safely.

- Although there is no mandatory federal requirement that HCPs take the training, it is highly encouraged.

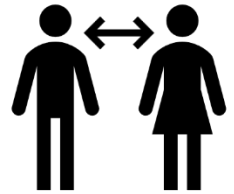
Center for Drug Evaluation and Research. (n.d.). Risk evaluation and mitigation strategy (REMS) for opioid analgesics. U.S. Food and Drug Administration. Retrieved June 7, 2022, from https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems

Pain Management CME Requirements

State	Requirement
Alabama	2 hours or 4 hours (for PA) every 2 years
Florida	2 hours or 10 hours (for PA) every 2 years
Georgia	3 hours or 3 hours every 2 years (for PA)
Kentucky	4.5 hours every 3 years
Louisiana	3 hours one-time only
North Carolina	3 hours every 3 years or 2 hours every 2 years (for PA)
Tennessee	2 hours every 2 years

State Requirements for Pain Management CME. NEJM Knowledge+. (2020, April 9). Retrieved June 15, 2022, from https://knowledgeplus.nejm.org/cme-moc/pain-management-and-opioids-cme/state-requirements-for-pain-management-cme/#:~:text=Beginning%20in%202020%2C%20physicians%20must,on%20safe%20opioid%20prescribing%20practices.&text=Licensees%20who%20prescribe%20controlled%20substances,prescribing%20practices%20every%20two%20years.

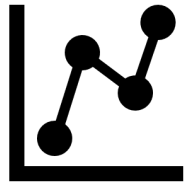
Why Is Patient Counseling Important?



- Patients can learn about the serious risks associated with opioid analgesic use, including addiction and overdose.
- Patients can learn how to take opioid analgesics safely.
- Patients can learn things to avoid while taking opioid analgesics, including alcohol, benzodiazepines, muscle relaxants, sleep medicines, etc.

Center for Drug Evaluation and Research. (n.d.). Risk evaluation and mitigation strategy (REMS) for opioid analgesics. U.S. Food and Drug Administration. Retrieved June 7, 2022, from https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems

Some Statistics To Consider



- Roughly 21% to 29% of patients prescribed opioids for chronic pain misuse them.
- Between 8% and 12% of people using an opioid for chronic pain develop an opioid use disorder.
- About 80% of people who use heroin first misused prescription opioids.

Vowles KE, McEntee ML, Julnes PS, Frohe T, Ney JP, van der Goes DN. Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis. Pain. 2015;156(4):569-576. doi:10.1097/01.j.pain.0000460357.01998.f1.

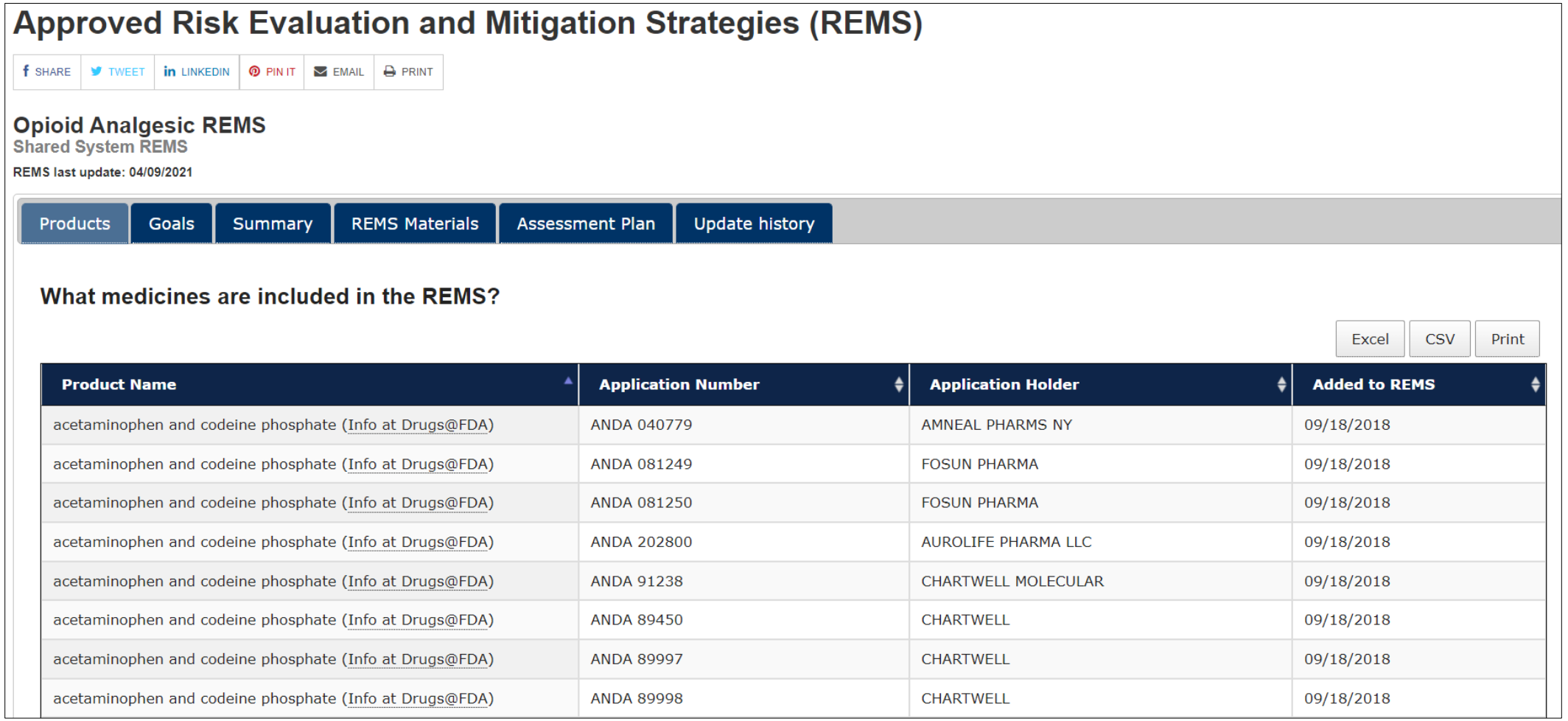
Opioid Products Included in the REMS

- A complete list of opioid products included in the REMS can be found on the FDA website.

- Documents and materials for HCPs and patients are also found on this website, along with a history of all the updates to the REMS.

Approved risk evaluation and mitigation strategies (REMS). accessdata.fda.gov. (n.d.). Retrieved June 7, 2022, from https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=17

Opioid Products Included in the REMS



Approved Risk Evaluation and Mitigation Strategies (REMS)

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Opioid Analgesic REMS

Shared System REMS

REMS last update: 04/09/2021

Products | Goals | Summary | REMS Materials | Assessment Plan | Update history

What medicines are included in the REMS?

Excel | CSV | Print

Product Name	Application Number	Application Holder	Added to REMS
acetaminophen and codeine phosphate (Info at Drugs@FDA)	ANDA 040779	AMNEAL PHARMS NY	09/18/2018
acetaminophen and codeine phosphate (Info at Drugs@FDA)	ANDA 081249	FOSUN PHARMA	09/18/2018
acetaminophen and codeine phosphate (Info at Drugs@FDA)	ANDA 081250	FOSUN PHARMA	09/18/2018
acetaminophen and codeine phosphate (Info at Drugs@FDA)	ANDA 202800	AUROLIFE PHARMA LLC	09/18/2018
acetaminophen and codeine phosphate (Info at Drugs@FDA)	ANDA 91238	CHARTWELL MOLECULAR	09/18/2018
acetaminophen and codeine phosphate (Info at Drugs@FDA)	ANDA 89450	CHARTWELL	09/18/2018
acetaminophen and codeine phosphate (Info at Drugs@FDA)	ANDA 89997	CHARTWELL	09/18/2018
acetaminophen and codeine phosphate (Info at Drugs@FDA)	ANDA 89998	CHARTWELL	09/18/2018

Approved risk evaluation and mitigation strategies (REMS). accessdata.fda.gov. (n.d.). Retrieved June 7, 2022, from https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=17

Opioid Products Included in the REMS (*subject to change)

Acetaminophen, Caffeine, and Dihydrocodeine Bitartrate	**Buprenorphine Transdermal System**
Benzhydrocodone and Acetaminophen	**Butorphanol Tartrate**
Aspirin and Oxycodone Hydrochloride	**Codeine Sulfate**
Aspirin, Butalbital, Caffeine, and Codeine	**Fentanyl**
Aspirin, Carisoprodol, and Codeine Phosphate	**Fentanyl Transdermal System**
Aspirin, Oxycodone Hydrochloride, Oxycodone Terephthalate	**Hydrocodone Bitartrate**
Buprenorphine	**Hydrocodone Bitartrate Extended-Release**

Approved risk evaluation and mitigation strategies (REMS). accessdata.fda.gov. (n.d.). Retrieved June 7, 2022, from https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=17

Opioid Products Included in the REMS (*subject to change)

Hydrocodone Bitartrate and Aspirin	**Morphine Sulfate**
Hydrocodone Bitartrate and Ibuprofen	**Morphine Sulfate Extended- Release**
Hydromorphone Hydrochloride	**Naloxone and Pentazocine**
Hydromorphone Hydrochloride Extended-Release	**Oxycodone Hydrochloride**
Ibuprofen and Oxycodone Hydrochloride	**Oxymorphone Hydrochloride**
Levorphanol	**Oxymorphone Hydrochloride Extended-Release**
Levorphanol Tartrate	**Tapentadol Hydrochloride**
Meperidine Hydrochloride	**Tapentadol Extended-Release**
Methadone Hydrochloride	**Tramadol Hydrochloride**

Approved risk evaluation and mitigation strategies (REMS). accessdata.fda.gov. (n.d.). Retrieved June 7, 2022, from https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=17

Patient Counseling Handout

- One of the documents available on the FDA website
- Contains information for patients regarding opioids, how to take them safely and things to avoid while taking opioids
- Valuable resource for patients to have on hand after verbal counseling

Approved risk evaluation and mitigation strategies (REMS). accessdata.fda.gov. (n.d.). Retrieved June 7, 2022, from https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=17

Patient Counseling Handout

Opioid Analgesic REMS **Patient Counseling Guide**

What You Need to Know About Opioid Pain Medicines

This guide is for you! Keep this guide and the Medication Guide that comes with your medicine so you can better understand what you need to know about your opioid pain medicine. Go over this information with your healthcare provider. Then, ask your healthcare provider about anything that you do not understand.

What are opioids?

Opioids are strong prescription medicines that are used to manage severe pain.

What are the serious risks of using opioids?

- Opioids have serious risks of addiction and overdose.
- **Too much opioid medicine in your body can cause your breathing to stop – which could lead to death.** This risk is greater for people taking other medicines that make you feel sleepy or people with sleep apnea.
- **Addiction** is when you crave drugs (like opioid pain medicines) because they make you feel good in some way. You keep taking the drug even though you know it is not a good idea and bad things are happening to you. Addiction is a brain disease that may require ongoing treatment.

Risk Factors for Opioid Abuse:

- You have:
  - a history of addiction
  - a family history of addiction
- You take medicines to treat mental health problems
- You are under the age of 65 (although anyone can abuse opioid medicines)

- Take your opioid medicine exactly as prescribed.
- Do not cut, break, chew, crush, or dissolve your medicine. If you cannot swallow your medicine whole, talk to your healthcare provider.
- When your healthcare provider gives you the prescription, ask:
  - How long should I take it?
  - What should I do if I need to taper off the opioid medicine (slowly take less medicine)?
- Call your healthcare provider if the opioid medicine is not controlling your pain. Do not increase the dose on your own.
- Do not share or give your opioid medicine to anyone else. Your healthcare provider selected this opioid and the dose just for you. A dose that is okay for you could cause an overdose and death for someone else. Also, it is against the law.
- Store your opioid medicine in a safe place where it cannot be reached by children or stolen by family or visitors to your home. Many teenagers like to experiment with pain medicines. Use a lock- box to keep your opioid medicine safe. Keep track of the amount of medicine you have.

Approved risk evaluation and mitigation strategies (REMS). accessdata.fda.gov. (n.d.). Retrieved June 7, 2022, from https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=17

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Naloxone (Narcan)

- Life-saving medication for patients to have on hand in case of overdose

- Highly suggested for patients with:
  - History of overdose
  - History of substance use disorder
  - Higher opioid doses (≥50MME/d)
  - Concurrent benzodiazepine use

NBCUniversal News Group. (n.d.). *Nation's top Doc wants the overdose antidote widely on hand. is this feasible?* NBCNews.com. Retrieved June 9, 2022, from https://www.nbcnews.com/health/health-news/surgeon-general-wants-naloxone-widely-hand-feasible-n866976

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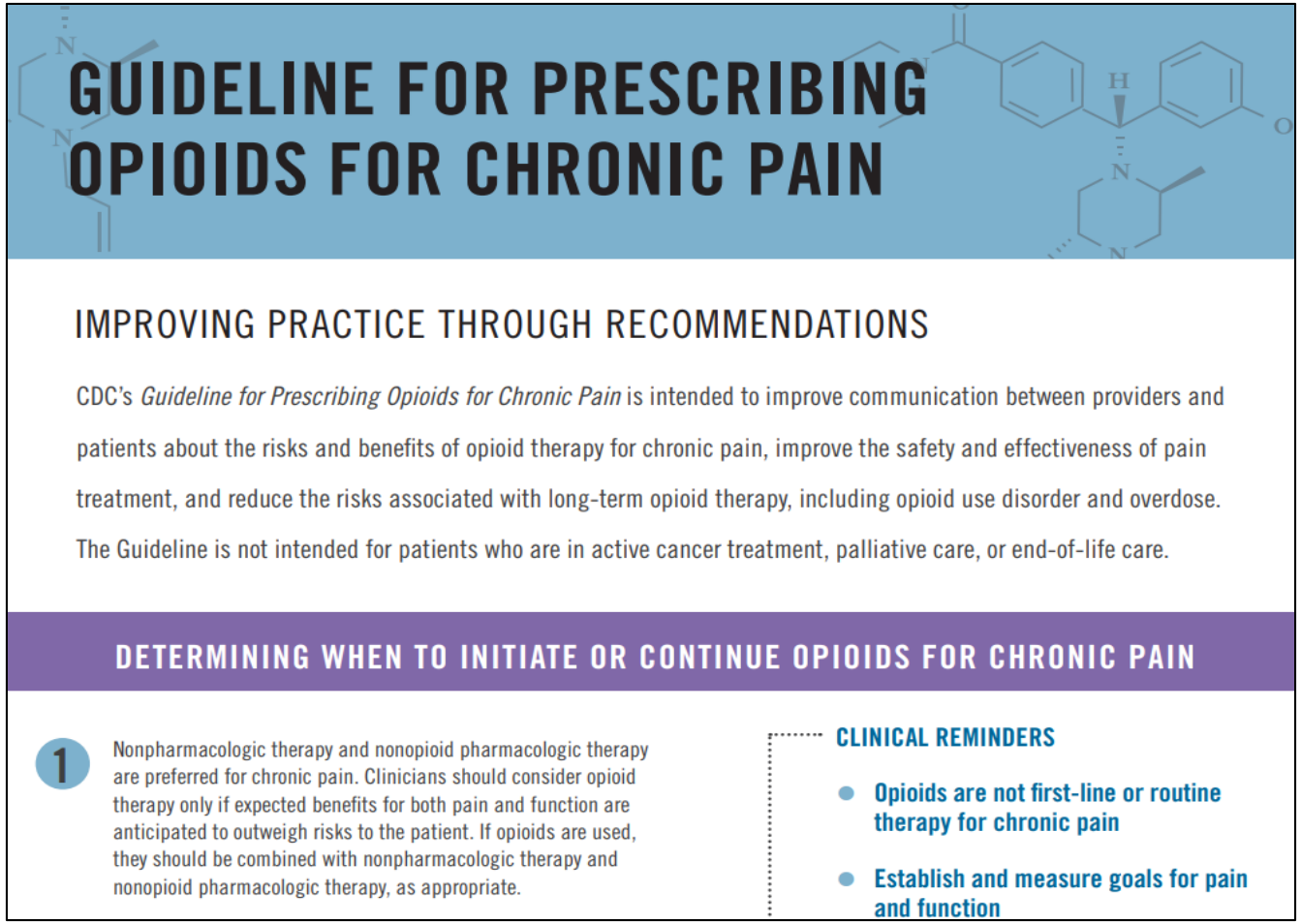
Guideline for Opioid Prescribing for Chronic Pain



GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

IMPROVING PRACTICE THROUGH RECOMMENDATIONS

CDC's *Guideline for Prescribing Opioids for Chronic Pain* is intended to improve communication between providers and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy, including opioid use disorder and overdose. The Guideline is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care.

DETERMINING WHEN TO INITIATE OR CONTINUE OPIOIDS FOR CHRONIC PAIN

1 Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

CLINICAL REMINDERS

- **Opioids are not first-line or routine therapy for chronic pain**
- **Establish and measure goals for pain and function**

Drug overdose - centers for disease control and prevention. (n.d.). Retrieved June 9, 2022, from https://www.cdc.gov/drugoverdose/pdf/guidelines_factsheet-a.pdf

Guideline for Opioid Prescribing for Chronic Pain

- Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain
- Discuss risks and establish treatment goals with patient prior to and during opioid therapy
- Set expectations
- Immediate-release prescribed initially

Drug overdose - centers for disease control and prevention. (n.d.). Retrieved June 9, 2022, from https://www.cdc.gov/drugoverdose/pdf/guidelines_factsheet-a.pdf

Guideline for Opioid Prescribing for Chronic Pain

- Follow-up and re-evaluate (1-4 weeks from initiation or dose increase)
- Review patient's state Prescription Drug Monitoring Program (PDMP) data before initiating and during treatment
- Consider urine testing prior to and during therapy (at least annually) to assess for other controlled substances and illicit drugs that may put a patient at risk for overdose
- Offer or arrange treatment for patients with opioid use disorder

Drug overdose - centers for disease control and prevention. (n.d.). Retrieved June 9, 2022, from https://www.cdc.gov/drugoverdose/pdf/guidelines_factsheet-a.pdf

Conclusion

- REMS is a drug safety program that the FDA can require for certain medications with serious risks of adverse events.
- The opioid analgesic REMS requires drug companies with approved opioid analgesics to offer education to HCPs in the form of CE activities and information to HCPs for patient counseling.
- Opioid analgesic REMS can help reduce the occurrence of serious adverse events associated with opioids (addiction, overdose) and encourage safe medication use.

Questions?

[How to Participate in Alliant's Readmissions Twitter Chat]

CMS 12th SOW Goals

Behavioral Health Outcomes & Opioid Misuse

- ✓ Promote opioid best practices
- ✓ Decrease high dose opioid prescribing and opioid adverse events in all settings
- ✓ Increase access to behavioral health services

Patient Safety

- ✓ Reduce risky medication combinations
- ✓ Reduce adverse drug events
- ✓ Reduce C. diff in all settings

Chronic Disease Self-Management

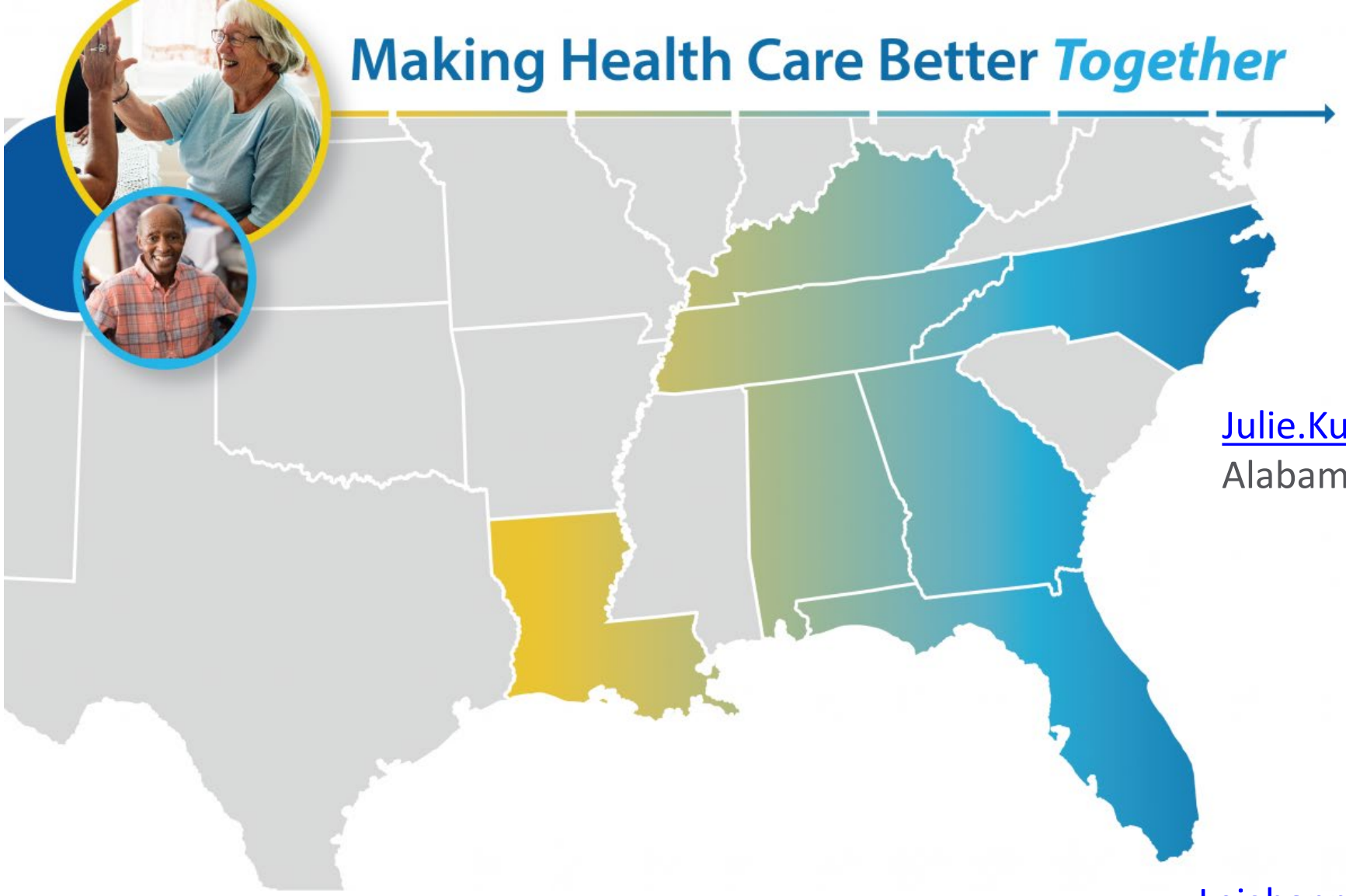
- ✓ Increase performance on ABCS clinical quality measures (i.e., aspirin use, blood pressure control, cholesterol management, cardiac rehab)
- ✓ Identify patients at high-risk for developing kidney disease & improve outcomes
- ✓ Identify patients at high risk for diabetes-related complications & improve outcomes

Quality of Care Transitions

- ✓ Convene community coalitions
- ✓ Identify and promote optical care for super utilizers
- ✓ Reduce community-based adverse drug events

Nursing Home Quality

- ✓ Improve the mean total quality score
- ✓ Develop national baselines for healthcare related infections in nursing homes
- ✓ Reduce emergency department visits and readmissions of short stay residents



Julie Kueker
Julie.Kueker@AlliantHealth.org
Alabama, Florida and Louisiana

Leighann Sauls
Leighann.Sauls@AlliantHealth.org
Georgia, Kentucky, North Carolina and Tennessee

Program Directors

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