Trends and Solutions in Wellness and Wellbeing

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Segal

Agenda

Introduction

Mental Health Care

Gender Affirming Care

Diabetes Management

Diabetes and Obesity

Musculoskeletal Care

Musculoskeletal Pain Management Challenges

Definition of Wellness and Wellbeing (Merriam-Webster)

the quality or state of being in good health especially as an actively sought goal

the state of being happy, healthy, or prosperous

The Eight Dimensions



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2024 Wellness Trends



What You're Up Against



Status quo bias

Inertia and fear of change



Complexity

People just don't understand



Hedonistic tendencies

Pleasure

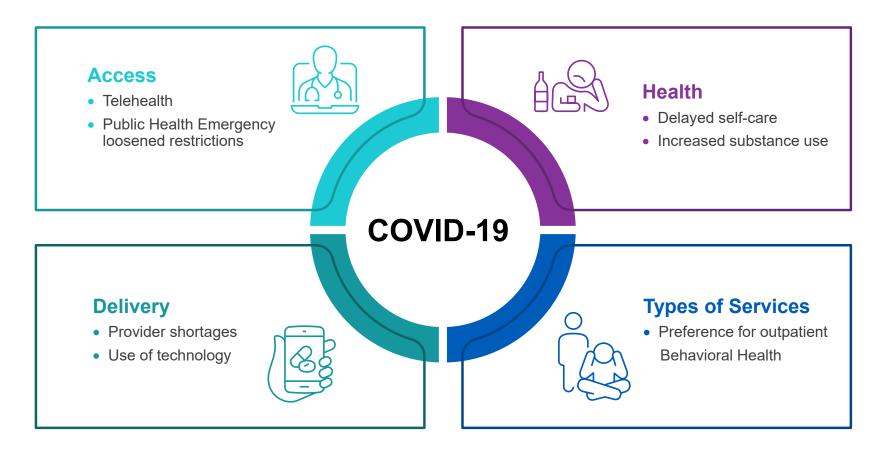


Information overload

Too many notifications

Mental Health Care

The Pandemic Effect



Emerging Mental Health Trends

Specialized substance use treatment

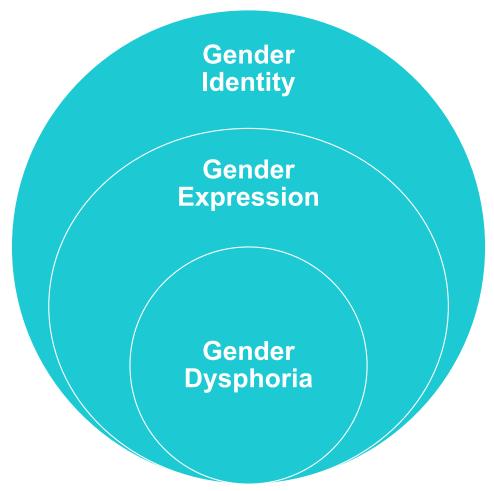
Assurance of provider quality

Measuring quantifiable outcomes

Spring Health Jen Foley, LMHC, CEAP Sr. Director, Clinical Partnerships

Gender Affirming Care

Terminology for Gender Affirming Care



Treatments for Gender Affirming Care

Psychotherapy Behavioral therapy Family counseling Puberty blockers Medication Hormone replacement therapy Drugs for hair loss or growth Appearance Surgeries (voice modification, tracheal shaving, etc.) enhancements Gender "Top surgery" affirmation "Bottom surgery" surgery

Treatment Considerations for Gender Affirming Care

Medical necessity of services

Age of participant

Cancer screenings based on gender

Reproductive preservation services

Reversal

Mental health support

Since gender dysphoria is a mental health condition, consider regulatory implications of plan design changes.

Gender Affirming

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Gender Affirming Care Highlights

Drugs used in transgender patients are commonly used for other reasons (i.e., hormone replacement therapy) and often times are already covered under a client's benefit.



Treatment in those < 18 years of age remains controversial.



According to the NY Times, new estimates based on CDC health surveys point to a stark generational shift in the growth of the transgender population of the United States.

Analysis found that about 122K children were diagnosed with gender dysphoria 2017 to 2021. (Reuters)

Gender-Affirming Care

- Transgender people may have health care concerns related to their transition. Because many want their physical appearance to match their gender identity, the transition process may include medical treatments, such as hormone therapy and gender confirmation surgery.
- Gender-affirming hormone therapy is used to minimize unwanted characteristics (e.g. facial hair or breasts).
- Masculinizing hormone therapy uses male hormones like testosterone to create a more masculine appearance.
- Feminizing hormone therapy uses anti-androgen hormones to block testosterone production along with female hormones such as estrogen.
- For adolescents who are unsure of their gender identity, puberty blockers or hormone blockers can help delay physical changes, such as breast development or facial hair growth, that don't match their gender identity.
- Psychotherapy is not required before gender-affirming medical and/or surgical treatment (GAMST) but may be helpful to some.
- Gender-affirming hormone therapy is not one-size-fits-all. The type and dosage of hormones must be individualized to each patient to get the best possible effects with the lowest amount of risk.

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Hormone Regimens – Transgender Patients

- Some people choose estrogen-based GAHT, which is also knows as feminizing hormone therapy.
- GAHT consists of estrogen, testosterone blockers, and progesterone (alone or in combination).
- These medications are commonly prescribed to trans women.
- Estrogen is available in tablet, injection and patch.
- Some products may commonly be excluded by clients.

Male-to-Female				
Estrogen	Example drug names			
Oral Estrogen	estradiol acetate, Estrace estradiol patch, Alora, Minivelle, Vivelle-Dot,			
Transdermal estrogen systems				
	Climara, Esclim, Menostar			
Injectable estrogens	Delestrogen, estradiol valerate, Depo-Estradiol, estradiol cypionate			

Hormone Regimens – Transgender Patients

Male-to-Female		
Antiandrogens	Example drug names	
Spironolactone	spironolactone, Aldactone	
GnRH analogs	Leuprolide acetate: Lupron Depot	
	(Ped), Eligard, Camcevi, Fensolvi	
	Triptorelin: Trelstar, Triptodur	
	Histrelin acetate:Vantas, Supprelin	
	LA, Zoladex	
	Goserelin acetate: Zoladex	
	Nafarelin acetate: Synarel	
Progesterone	medroxyprogesterone, Provera,	
	Depo-Provera	
Finasteride	Finasteride 1mg (generic for	
	Propecia) [5mg (generic for Proscar)	
	is used mostly for BPH], Dutasteride	
	(Avodart)	
Dutasteride	for Proscar) is used mostly for BPH],	
	Dutasteride (Advodart)	

- Finasteride is noted in several resources for treatment of hair loss in transwomen and for male pattern baldness in transmen.
 - Finasteride can also be used to regulate body hair growth, sebaceous glands, and skin consistency.
 - > Finasteride has also been used to reduce masculinizing properties in male-to-female transgender youth patients.
- Some of these products can also be used to delay puberty in adolescents and preadolescents.
- Some products may commonly be excluded by clients.

Hormone Regimens – Transgender Patients

Female-to-Male				
Testosterone	Example drug names			
Injectable testosterone	testosterone cypionate, Depo- Testosterone, Delatestryl, testosterone enanthate, Xyosted, Aveed			
Transdermal: testosterone gel or patch	testosterone gel, AndroGel, Fortesta, Testim, Vogelxo, Androderm, Axiron			
Other Testosterone				
Implantable testosterone	Testopel (pellet)			
Buccal testosterone	Striant (buccal system)			
Nasal testosterone	Natesto (nasal pump)			
Oral testosterone	Jantezo, Kyzatrex, Tlando (capsule)			

- Some people choose Testosterone-based GAHT, or masculinizing hormone therapy, as part of their gender-affirming care.
- Testosterone is one of sex steroid hormones involved in various physical changes in the body like hair growth, changes in voice, etc.
- There are several different forms of testosterone to choose from.
- Some products may commonly be excluded by clients.

Diabetes Management

Diabetes & Pre-Diabetes

Diabetes by the Numbers — National Norms

1 in 9 Americans has diabetes1

94.3% of those with diabetes are type 2 diabetics²

38% of adults have pre-diabetes²

25% of all health spending

is from people diagnosed with diabetes³

Per capita spend

for people with diabetes is 2.6x higher than for those without diabetes³

People with diabetes are twice as likely to have a stroke as those without diabetes1

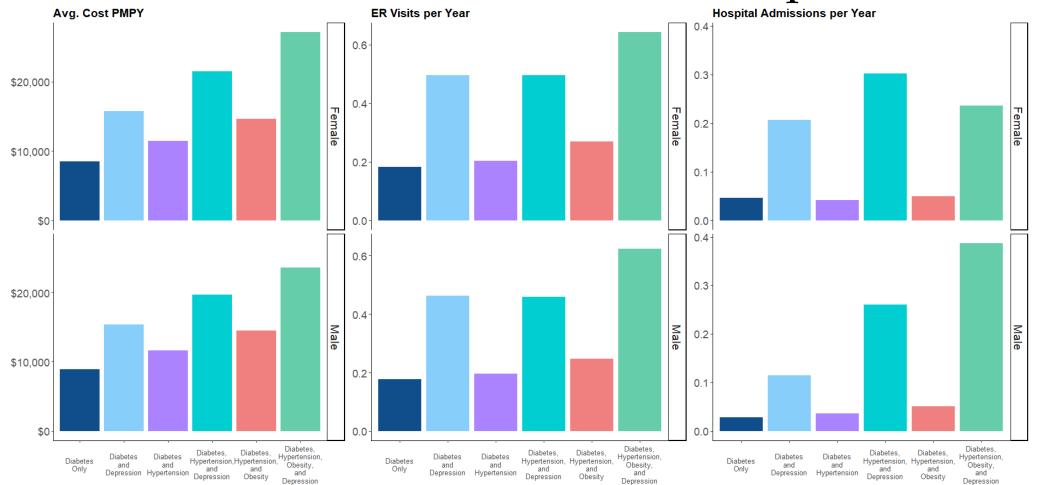


American Diabetes Association. Statistics About Diabetes. http://www.diabetes.org/diabetes-basics/statistics/?loc=db-slabnav

² Centers for Disease Control and Prevention National Center for Chronic Disease Prevention and Health Promotion. https://www.cdc.gov/diabetes/data/statistics-report/index.html

³ Economic Costs of Diabetes in the U.S. in 2022 https://pubmed.ncbi.nlm.nih.gov/37909353/#:~:text=For%20cost%20categories%20analyzed%2C%20care,which%20are%20attributable%20to%20diabetes

The Intersection of Diabetes and Depression



Source: Segal's SHAPE data warehouse

First-Line Therapy

Medical Nutritional Therapy

- The American Diabetic Association (ADA) recognizes that through lifestyle modification and medical nutrition therapy, type 2 diabetes can go into remission.
- The ADA and the UK National Health Service (NHS), through Diabetes Remission Clinical Trial (DiRECT), have amended their recommendations to include medical nutrition therapy as front-line therapy for type 2 diabetes.





The Value of Health Coaching

- Needs whole person care, not just medication access
- Health coaching is of paramount importance to:
 - Build ongoing, trusted relationship with the recipient of the medication
 - Monitor the medication side effects and interactions
 - Address the medication goal areas and adherence
 - Discuss dosages, interactions, side effects, and concerns related to the medication
 - Advocate, speaking directly with physician or pharmacy
 - Monitor and help manage medication tolerance and contraindications
 - Provide in-person or virtual access points

The Diabetes Solutions Landscape



All outcomes hinge on identification and engagement.

Strategies for Value

- Coordination of vendors
- Clinical rigor
- Performance guarantees
- Clear, targeted communications
- Monitor ROI
- Avoid pitfalls
 - Technology trends
 - Aggressive sales tactics
 - Confusion about benefits
 - Unproven outcomes
 - Emerging tech startups

Population Health and Diabetes

Diabetes Education and Awareness

- Materials focus on:
 - Risk factors and prevention
 - Condition management
 - Strategies for prevention and self-care
- Articles, videos, webinars, and interactive tools

Risk Assessment and Screening

- Risk assessment tools considering age, weight, family history, and lifestyle habits
- By identifying individuals at higher risk, organizations can target interventions more effectively and provide personalized support

Behavioral Change Support

- For healthier habits and effective diabetic management
- To encourage adherence to medication, diet, exercise, and other lifestyle recommendations:
 - Goal-setting tools
 - Self-monitoring features
 - Reminders
 - Incentives

Wellness Programs Supporting Diabetes

Nutrition and **Meal Planning**

- Wellness programs include diabetes-specific meal planning tools
- Healthy recipes, meal trackers, carbohydrate counting guides, and personalized dietary recommendations based on individual preferences and dietary restrictions

Blood Glucose Monitoring and Management

- Most diabetes point solutions include tools for tracking and managing blood glucose levels, such as glucose monitoring apps, connected devices, and integrated health platforms
- These tools allow individuals to monitor their blood sugar levels, track trends over time, and share data

Remote **Monitoring and Telehealth**

- Allows individuals to receive personalized care and access support
- Identifies real-time trends and allows speedy intervention

Other Prevention Strategies

Well-Being Activities	Benefit Design	Vendor Partnership	Communication
 Well-Being Activities Health risk assessments and biometric screening Lunch & Learn sessions Online health education classes Walking groups Competitions Lifestyle coaching Chronic condition coaching Gym memberships 	 Remove limitations on nutritional counseling Evaluate bariatric surgery benefits PBM coverage of weight loss medication Incentives/penalties 	 Vendor Partnership Well-being platforms Diabetes Prevention Program (DPP) Digital Therapeutics 	 Communication Communication is ongoing Behavior economics/science
 Plan-reimbursed fitness trackers 			

Diabetes and Obesity

Diabetes Prevalence

11.3% of total US population have diabetes.

Losing 5-7% of their body weight and added 150 minutes of exercise per week can reduce risk of developing diabetes by up to 58%.



Potential market for new drugs is significant

What are GLP-1 Medications?

GLP-1 is a hormone found naturally in our bodies that targets the area of the brain that regulates appetite and is insufficient in people who have

type 2 diabetes. **Diabetes Weight Loss** Medications Medications mimic GLP-1 mimic GLP-1 hormone and hormone and help lower help regulate blood sugar appetite

What Names do we Know for GLP-1 Agonists¹?

- Diabetes drugs in the GLP-1 agonists class are generally taken by a shot (injection) given daily or weekly and include:
 - Dulaglutide (Trulicity) (Eli Lilly)
 - Exenatide (Bydureon BCise and Byetta) (AstraZeneca)
 - Semaglutide (Ozempic, Rybelsus oral) (Novo Nordisk)
 - Liraglutide (Victoza) (Novo Nordisk)
 - Lixisenatide (Adlyxin) (Sanofi)
 - Tirzepatide (Mounjaro²) (Eli Lilly)
- Pharma developing more medications based on the success of these medications in treating diabetes

History of GLP-1 Medications

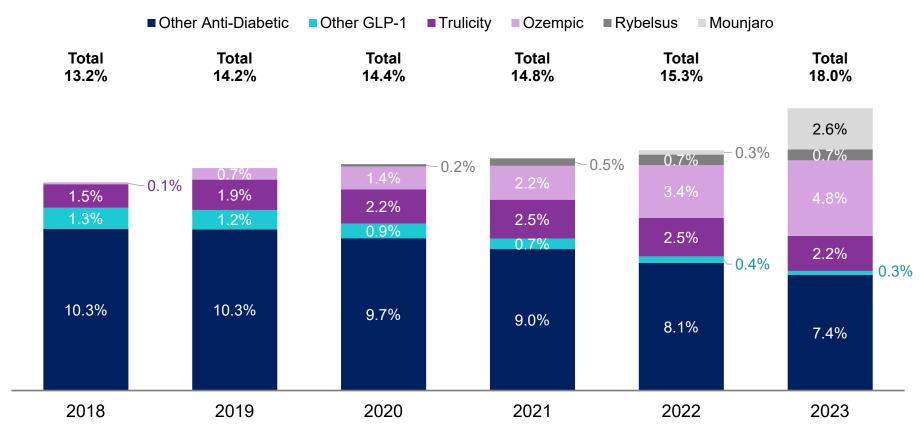
Until recently GLP-1's considered a second-line agent to treat diabetes

2021, ADA recommends prescribing **GLP-1s to reduce health** complications regardless of A1C or metformin use

2023 ADA guidelines emphasizes both supporting higher weight loss and focusing on obesity as chronic disease

Led to increased utilization of GLP-1s for diabetes AND weight loss

Plan Spending on Anti-Diabetic Medications with Weight Loss is Rising Steadily



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Utilization Concerns

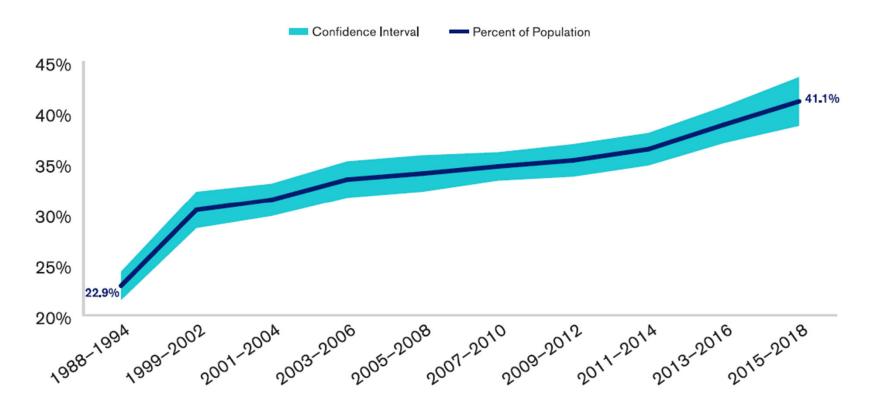
- Off label use of diabetes GLP-1 therapies (i.e. Ozempic) for weight loss.
- Social media has been a big contributor to using Ozempic for weight loss which, in turn, has caused drug shortages.
- PBMs are offering utilization management programs to curb off-label spend for the GLP-1 medications.
- GLP-1s are in the top drug spend for many plan sponsors in 2024.



Potential market for new drugs is significant. What does your current utilization look like?

Obesity and the GLP-1 Effect

The Obesity Rate of the U.S. Population Has Almost Doubled in Recent Decades



Obesity Prevalence

42% of US adults are obese

Obesity is recognized as a chronic disease since 2013

Potential market for new drugs is significant

Are Plans Covering Weight Loss Drugs and What Is Impact?

- Employers Health, a large group-purchasing organization for pharmacy benefits for 2021 reported 60% of clients exclude obesity drugs and 25% cover them with a PA.
- Medicare does not cover obesity drugs, but does cover bariatric surgery and intensive behavioral therapy.
- Nearly half of large employers (49%) expect to cover the new weight loss medications as part of their health plans, according to the <u>2024 Large</u> <u>Employers' Health Care Strategy and Plan Design Survey</u> by the Business Group on Health, which queried 152 larger employers.
- The survey of 502 employers by Accolade a company that provides healthcare programs for employers, and research firm Savanta said 43% of the employers it polled could cover GLP-1 drugs in 2024 compared to 25% that cover them now. (Reuters)



What Drugs are the FDA Approved Anti-Obesity Medications?

FDA approved anti-obesity medications include the following:

- Older Anti-obesity Medications (AOMs)
 - Phentermine (Adipex, Lomaira) (Teva Pharmaceuticals, KVK Tech)
 - Phentermine/ topiramate ER (Qsymia) (Vivus)
 - Naltrexone/bupropion HCL (Contrave) (Curax Pharmaceuticals)
 - Orlistat (Xenical, Alli otc) (CHEPLAPHARM, GlaxoSmithKline)

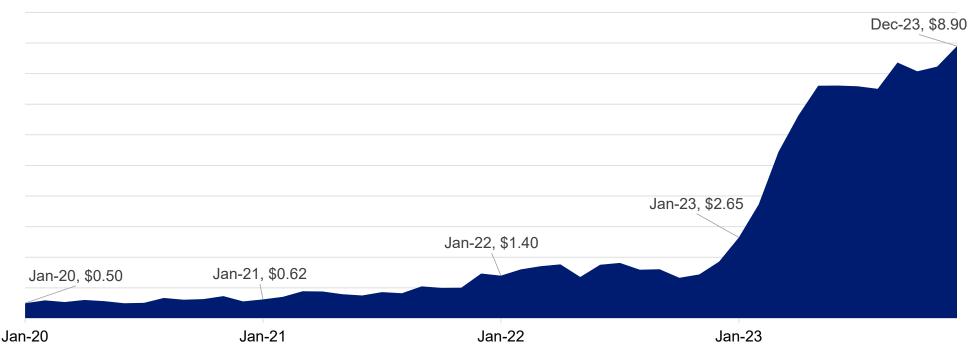
- Newer Anti-obesity Medications (AOMs)
 - Semaglutide (Wegovy) (Novo Nordisk)
 - Liraglutide (Saxenda) (Novo Nordisk)
 - Tirzepatide (Zepbound) (Lilly)
 - Imcivree (setmelanotide) (Rhythm Pharmaceuticals and Genpharm)

Obesity GLP-1 Medication Costs Compared to Diabetes GLP-1 Medications

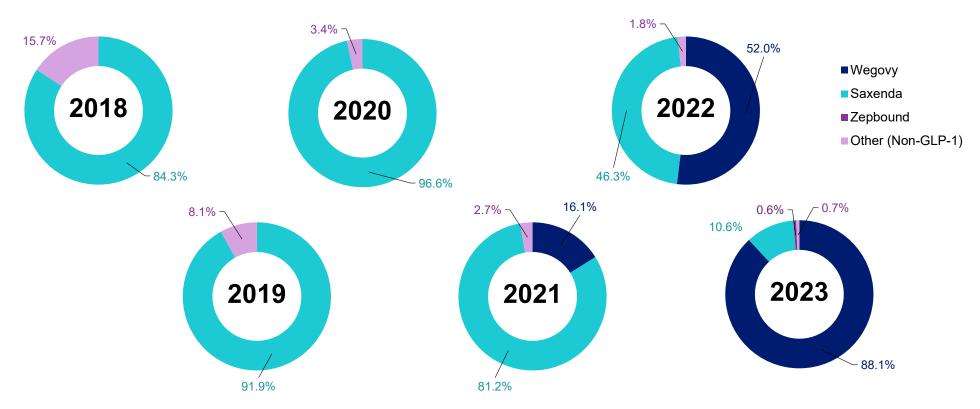


Dramatic Increase in Anti-Obesity Medication Spending due to GLP-1s

Segal Book-of-Business AOM (Median Allowed Per Member Per Month)



Plan Spending on Weight-Loss Medication Continues to Shift Towards GLP-1s



Source: Segal SHAPE, Segal's data warehouse, 2018 to 2023

Weight-loss Options Vary in Cost and Effectiveness

Avg weight loss at ~ 1 year (% reduction in body weight)

Est. List Price (for one year of treatment)

Traditional Diet & Exercise Programs

0-5%

\$500

Chin, S., Keum, C., Woo, J. et al. Successful weight reduction and maintenance by using a

smartphone application in those with overweight

and obesity. Sci Rep. 2016; 6, 34563, Noom list

Provider-Led
Clinical Weight Loss

13%

\$1,800

AcKenzie AL, et al. Nutrients. 2021; 13(3):749
Outcomes among one year completers, Virtalist price

GLP-1 Drugs

Bariatric Surgery

20%+

\$12,000+

Wilding JPH, Batterham RL, Calanna S, et al. Once-Weekly Semaglutide in Adults with Overweight or Obesity. N Engl J Med. 2021;384(11):989-1002.

Novo Nordisk; list price. https://www.novocare.com/wegovy/let-us-help/ explaining-list-price.html - \$1309.42 per package. Accessed 10/18/22 NTMC, "How much does bariatric surgery cost," Accessed 1/25/2023, Maciejewski ML, Arterburn DE, Van Scoyoc L, Smith VA, Yancy WS Jr, Weidenbacher HJ, Livingston EH, Olsen MK. Bariatric Surgery and Long-term Durability of Weight Loss. JAMA Surg. 2016 Nov 1;151

Are there potential longer-term savings from lower obesity rates vs. near-term Rx costs?

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Various PBM Cost Management Strategies

Use utilization management to ensure the diabetic GLP-1 drugs are only used for patients with diabetes

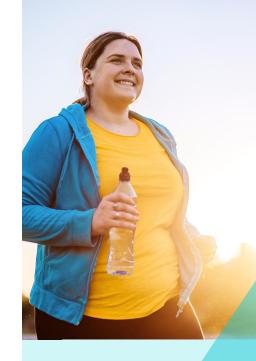
Smart logic to screen out patients who have diabetes. Smart logic utilizes both ICD diagnosis codes (if available) and prescription claims history to bypass PA requirements.

Doctor office to confirm diagnosis and "attest" to it in a PA case

Move from step therapy to prior authorization approach

Requiring documentation versus attestation for PA criteria

Requiring ICD-10 information as part of criteria



Be sure to consider any potential rebate impact

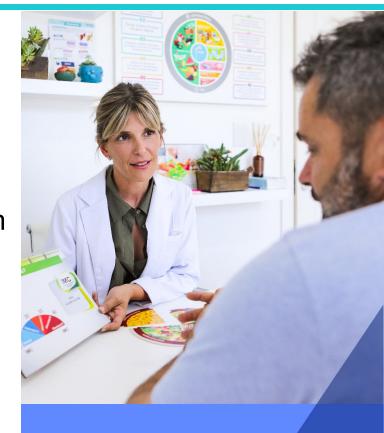
The Bigger Picture for Managing Obesity

- Negotiate lowest-net-cost PBM formulary changes.
- Provide educational support for appropriate and safe exercising.
- Offer access to virtual coaching.
- Implement accountability check-ins with patients.
- Consider implementing stricter coverage to target smaller group of plan participants.



The Bigger Picture for Managing Obesity

- Seek outcomes-based performance guarantees with PBMs when adding coverage of these highcost anti-obesity meds tied to achieving minimum average weight loss amounts (e.g., at least 10% weight loss after 6 months use).
- Patients need whole person care, not just medication access.
- Health coaching is of paramount importance.
- Continue behavior change coaching for 1-2 years post treatment.
- Build and activate ongoing support network for each participant.



Musculoskeletal Care

What are Musculoskeletal Disorders?

Musculoskeletal Disorders (MSD) are injuries or disorders of the muscles, nerves, tendons, joints, cartilage and spinal discs.

Common MSDs

- Muscle/Tendon Strain
- Tendonitis
- Ligament Sprain
- Rotator Cuff Injury
- Carpal Tunnel
- Trigger Finger
- Back Injury
- Nerve Compression
- Degenerative Disc
- Arthritis



Time and exposure to risk factors can lead to MSD

- Ergonomics
- Repetition Posture Force
- Poor Health Obesity
- Working Conditions
- Genetics
- Age



Segal

How are Musculoskeletal Disorders Treated?

Prevention

- Education
- Exercise
- Nutrition
- Weight management
- Stretching
- · Avoidance of aggravating activities
- Proper body mechanics
- Work ergonomics
- Safe work environment
- Avoid smoking

Acute

- Diagnosis/treat
- Pain management
- Physical and occupational therapy

Chronic

- Pain management
- Nonsteroidal or steroidal medications
- Injections
- Infusions
- Cognitive behavioral therapy
- Weight loss
- Spinal manipulation
- Massage
- Acupuncture

Surgical

- Treatment decision support
- Surgeon selection
- Device selection
- Pre- and postoperative rehab
- Pain management

Musculoskeletal Disorders in Multiemployer Industries

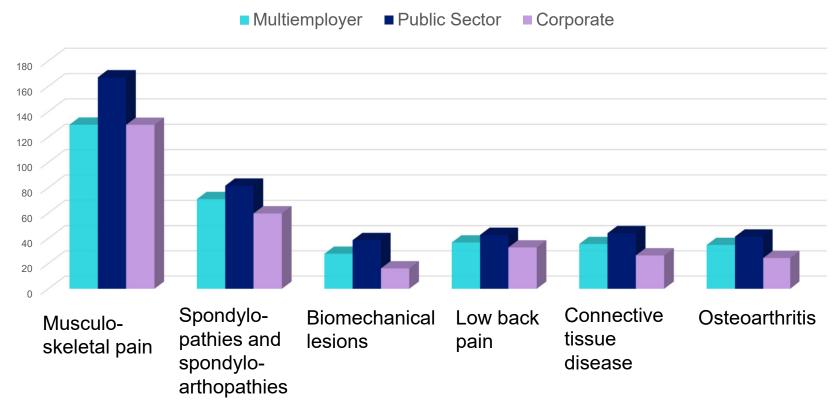
Most Prevalent Musculoskeletal Conditions, per Thousand Participants		
Condition	Prevalence	
Musculoskeletal pain, not low back		
pain	130	
Spondylopathies/spondyloarthropathy	71	
Low back pain	37	
Other specified connective tissue		
disease	36	
Osteoarthritis	35	
Biomechanical lesions	28	
Tendon and synovial disorders	22	
Other specified joint disorders	18	
Other specified bone disease and		
musculoskeletal deformities	9	
Acquired foot deformities	7	

Most Costly Musculoskeletal Conditions, per Thousand Participants	
Condition	Cost
Osteomyelitis	\$5,994
Osteoarthritis	\$3,735
Pathological fracture, initial encounter	\$2,859
Spondylopathies/spondyloarthropathy	\$2,729
Rheumatoid arthritis and related disease	\$2,061
Neurogenic/neuropathic arthropathy	\$1,843
Acquired foot deformities	\$1,733
Juvenile arthritis	\$1,731
Aseptic necrosis and osteonecrosis	\$1,658
Tendon and synovial disorders	\$1,555

Source: Segal's SHAPE Database

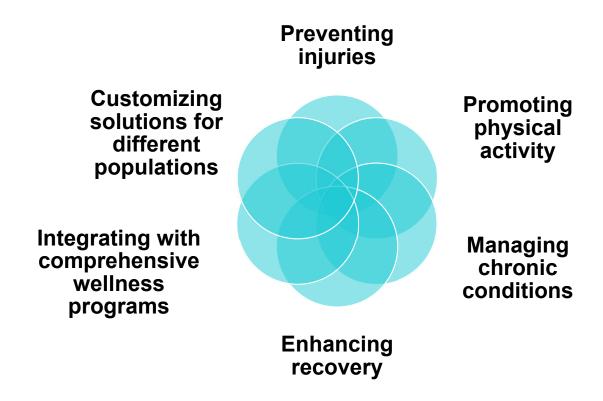
Musculoskeletal Disorders Treatment Across Industries

Most Common Musculoskeletal Conditions, per Thousand Participants



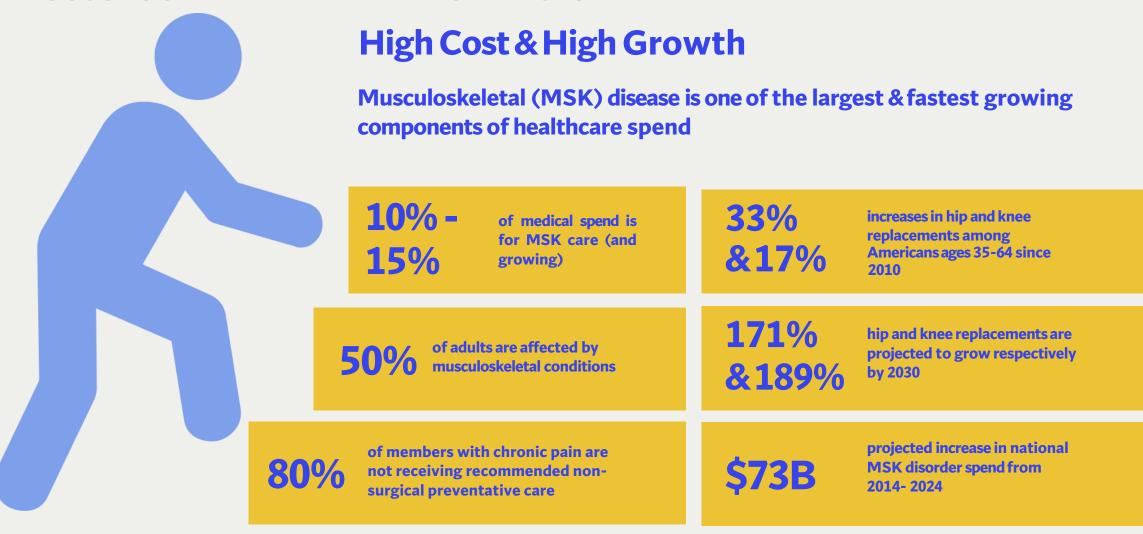
Source: Segal's SHAPE Database

Integration of Musculoskeletal Solutions with Wellness Programs



Nimble Health John Lawrence Executive Director

MUSCULOSKELETAL HEALTH SERVICES



OVERVIEW

Nimble Healthis a patient-first musculoskeletal concierge program

We proactively identify and engage with members very early, offering clinical decision support, valuable digital tools, care navigation and concierge scheduling to high-quality providers, acting as a trusted guide to members along their entire MSK care journey.



Nimble Health core competencies & services

Proactive
Member
Identification
& Engagement

Member
Education/
Decision Support
by MSK-Trained
Nurse
Health Coaches

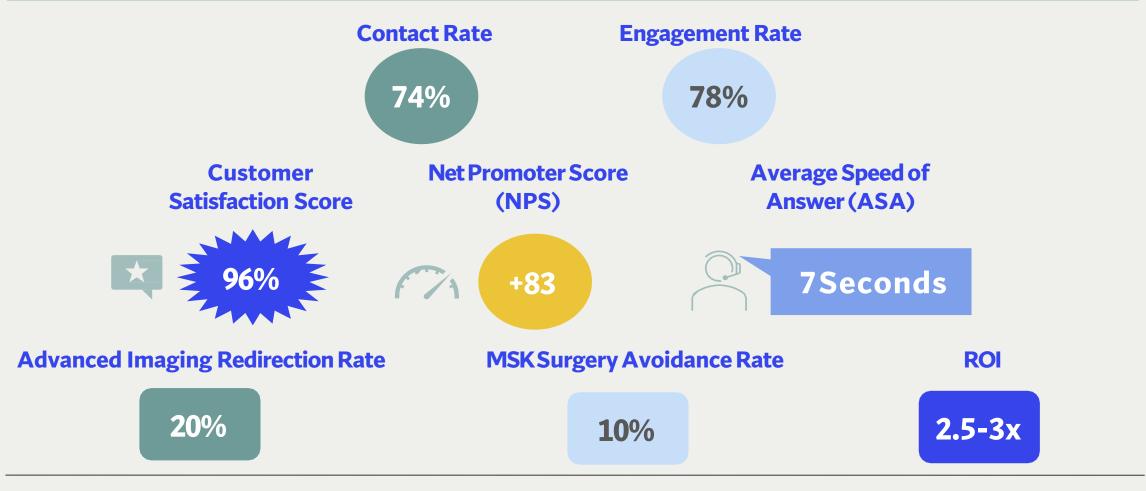
Provider
Assessment &
Navigation

Concierge Scheduling*
(Advanced imaging,
PT, Virtual PT, Pain
Management, Virtual
Expert Opinions &
Surgery)

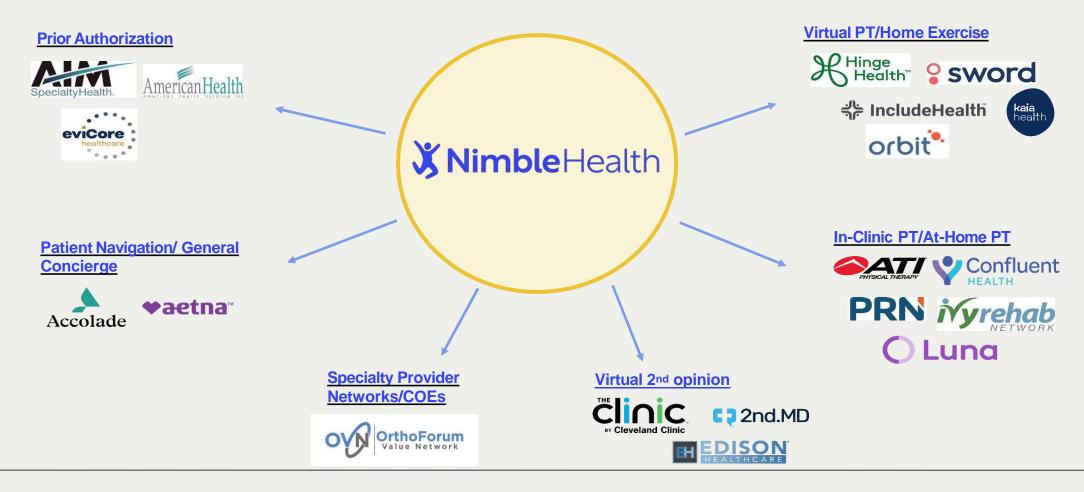
Pre/Post Operative Assistance Opioid
Awareness
& Education

2023 BOOK OF BUSINESS PERFORMANCE METRICS

Nimble Health has successfully worked with patients to help them access a variety of services and to support their entire MSK journey.

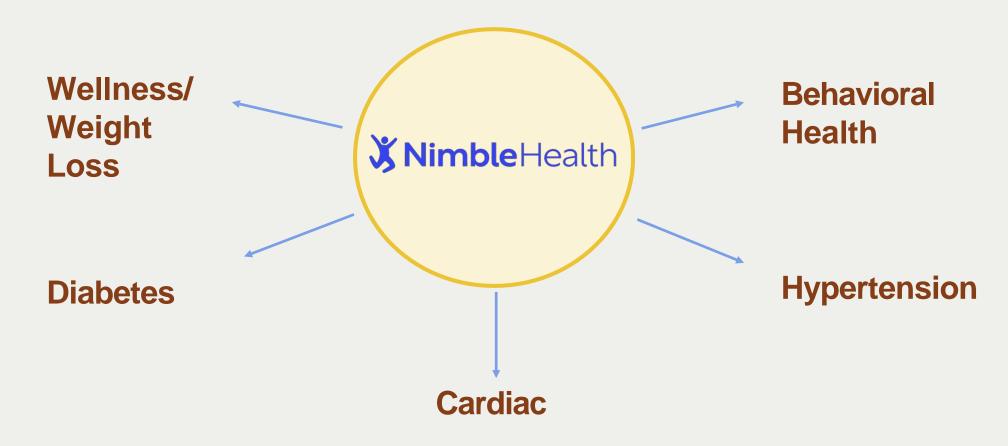


Nimble Health integrates & partners with various point solutions to offer a seamless end-to-end MSK program





Common MSK Comorbidities – Opportunities to Increase Member Participation in Other Chronic Disease Management Programs



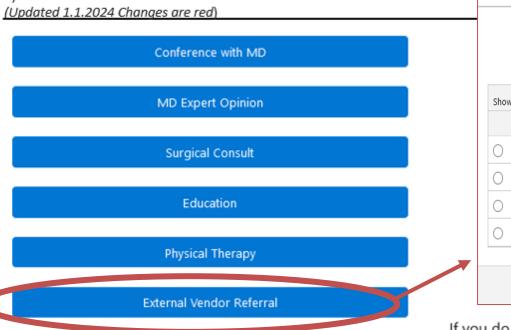
Complete

CLOSING OPTIONS

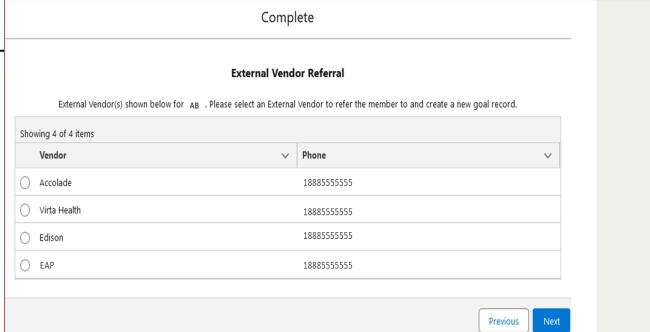
Client A | Health Plan | (Industry Type) | VSO: Cleveland Clinic | VEP: Include

Other Client Details:

- Accolade
- Virta Diabetes, Obesity
- 3) Edison COE
- 4) EAP



Other



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Exit

Nimble Health's Simplified Case Rate



Services Included:

- ✓ Member Engagement, Clinical Decision Support and Education Services
- ✓ Digital Tools & Educational Materials
- ✓ Provider Assessment & Navigation (advanced imaging, physical therapy, painmanagement, virtual expert opinions & surgery)

- **✓** Concierge Scheduling
- ✓ Pre & Post-Op Patient Support
- ✓ Opioid Awareness & Education with Acute Post-Op Monitoring

Case rate covers unlimited MSK interactions and services over a rolling 12-month period



Summary

Nimble Health can engage more members, provide more services, deliver a better experience, and produce stronger financial results

Value

- √ Major components of the MSK journey wrapped into a single solution
- **✓** Best in class engagement levels
- **✓** Higher adoption of other key chronic care programs
- **✓** Proven track record of market-leading member satisfaction
- **✓** Flexibility to integrate with your existing vendor partners

Benefits

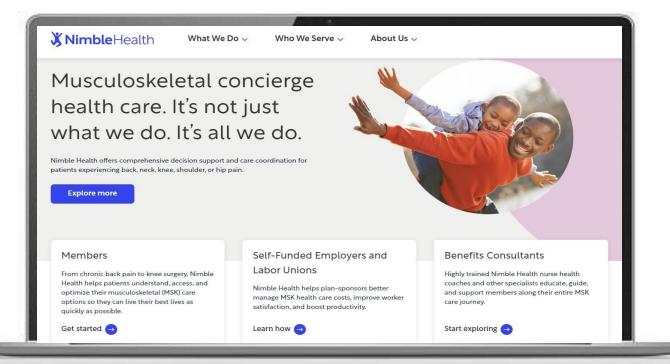
- \checkmark Singular focus on a top 3 medical cost driver
- **✓** Improved program awareness & higher utilization results
- **√** Strong financial results & ROI
- **✓** Administrative ease
- \checkmark A happier, healthier member

X NimbleHealth

For more information on what we and how we help members with their musculoskeletal health care

www.Nimble-Health.com





83

net promoter score

96%

member satisfaction score

74%

contact rate

78%

engagement rate

Musculoskeletal Pain Management Challenges

Background Musculoskeletal Pain

Types	Affect acute or chronic pain that affects bones, muscles, ligaments, tendons, and even nerves
Symptoms	Aching, stiffness, burning sensations, fatigue, muscle twitches, pain that worsens with movement, sleep disturbances
Causes	Bone fractures, joint dislocation, direct blows to muscles, bones or joints, overuse injuries, poor posture, sprains
Diagnosis	Blood tests, CT scans, MRI, X-rays
Prevalence	54% of adults in U.S. (126.6 million individuals over age of 18 years) affected

Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6348332/

MSK Subgroups Cost Utilization

54% of adults in U.S. (126.6 million individuals over age of 18 years) are affected.

- Cost Utilization in Subgroups:
- Wear and tear conditions
 - Strains, sprains, ruptured discs in the spine; or degenerative disease of the joints (63.5%)
- Major trauma
 - Fractures and crush injuries (18.6%)
- Autoimmune conditions
 - Rheumatoid arthritis (16.9%)
- Within wear and tear conditions cost:
- Back and neck or spine accounts for 42%
- Only back conditions make up 29%
 - > Example: patient spend more than \$100,000 for back conditions

Pharmacologic Treatments

Nonopioid Analgesics

- Acetaminophen PO/IV

NSAID:

- Ibuprofen PO
- Naproxen PO
- Ketorolac IV
- Diclofenac Topical

COX-2 inhibitors:

- Celecoxib PO

Opioid

- Morphine PO/IV
- Fentanyl IV/Sublingual/TTS
- Meperidine IV
- Oxycodone PO/IV
- Methadone PO
- Buprenorphine TD Patch
- Tramadol PO/IV
- Codeine PO
- Tylenol-3 PO

Adjuvants Analgesics

Antidepressants:

- Amitriptyline PO
- Nortriptyline PO
- Duloxetine PO

Anticonvulsants:

- Gabapentin PO
- Pregabalin PO
- Carbamazepine PO

Others:

- Dexamethasone PO/IV
- Prednisolone PO
- Lidocaine TD
- Capsaicin TD

Opioid Drugs Fast Facts

79,117

Americans died from drug-involved overdose between January and September of 2022¹

Members abusing Opioids will have

the Total Healthcare Costs²

70% of abused Rx drugs are provided by friends and family³

- The total economic burden from the Opioid epidemic includes not only healthcare costs, but mortality, criminal justice, family assistance, education, and lost productivity in the labor force.4
- A national employer survey in 2019 found that of the 75% of US employers who were affected by employee use of Opioids. only 17% were well prepared to handle the issue. 4
- Up to 1 out of 4 patients on long-term Opioid therapy struggle with addiction.⁵
- Although prescription Opioid use is legal and prescribed for individuals with chronic or acute pain, either prescribed or illicit use of Opioids can lead to Opioid Use Disorder (OUD), a disease characterized by the chronic use of Opioids leading to impairment or distress.

Opioid Use Timeline

Extended release products were FDA approved from 1987 to 1995:

- MS Contin approved by FDA 7
- Duragesic approved by FDA Transdermal Fentanyl patch
- Oxycontin approved by FDA
 - - American Pain Society 9
 - Quality *Improvement* Guidelines for the Treatment of Acute Pain and Cancer Pain
 - Advocates more aggressive pain management practices

1998

- Federation of State Medical Boards 10
- Model Guidelines for the Use of Controlled Substances for the Treatment of Pain
- Recommends more liberal pain management and policies reassuring doctors won't face regulatory action for prescribing Opioids
- Purdue did not submit OxyContin promotional video for FDA review before use 13, 14

1999

- California Assembly Bill 7913
- · "Every health facility licensed pursuant to this chapter shall, as a condition of licensure, include pain as an item to be assessed at the same time as vital signs are taken."

The Joint Commission on the Accreditation of Healthcare Organizations¹¹

- Pain Management Standards
- Department of Veterans Affairs¹²
- Pain as the 5th Vital Sign Toolkit
- Booklet published by the Joint Commission sponsored by Purdue Pharma "there is no evidence that addiction is a significant issue when persons are given Opioids for pain control" 15

- FDA Warns Purdue Pharma about misleading advertisements
- Purdue forced to remove advertisements from The Journal of the American Medical Association

2007

- Purdue, maker of Oxycontin, pleads guilty to misbranding—downplaying the potential for addiction
- Purdue pays over \$600M in fines¹⁶

2016

Centers for Disease Control and Prevention (CDC) creates Guideline for Prescribing Opioids for Chronic Pain

2019

 FDA takes new enforcement actions to combat the illegal online sales of Opioids

2022

 FDA announces the establishment of the FDA Overdose Prevention Framework to prevent drug overdoses and reduce deaths

2023

 FDA approves the first OTC naloxone nasal spray, expanding access for Opioid overdose

1987 1995 1998-1999 2000 2003-2016 2019-2023

X Segal 62

Understanding The Problem

How Did We Get Here



In the early 1990s, medical guidelines encouraged the aggressive treatment of acute and chronic pain



Since 1999, the amount of prescription Opioids sold in the United States nearly quadrupled.6



Drug overdose deaths have risen fivefold over the past 2 decades. In 2021, 106,699 deaths occurred. 7

- Since the 1990s, when the volume of Opioids prescribed to patients began to grow, the number of overdoses and deaths from prescription Opioids has also increased. As the volume of Opioids prescribed for pain has increased, the amount of pain reported in the U.S. has not changed in comparison.
- Opioids were involved in 68,630 overdose deaths in 2020 (74.8% of all drug overdose deaths).
- Illicitly manufactured fentanyls were most commonly involved Opioids in overdose deaths.

https://www.cdc.gov/drugoverdose/epidemic/index.html 8

Flaws in Plan Design*

- The majority of Opioids are available as generics and are inexpensive
- Many plans make Opioids more accessible than alternative treatments including ²⁶
 - Physical therapy
 - Alternative therapies such as chiropractors and acupuncture
 - More expensive but potentially less addictive medications



Opioid management may raise considerations related to compliance with the Mental Health Parity and Addiction Equity Act (MHPAEA) discussed further

PBM Strategies*

- Fraud Waste & Abuse Programs
 - Pharmacy / Prescriber Lock
 - Member / Prescriber outreach
- Utilization Management Solutions:
 - Quantity Limits
 - Step Therapy Edits
 - Prior Authorization (PA)
 - Other: Duration/Concomitant Use Edits



^{*} Opioid management may raise considerations related to compliance with the Mental Health Parity and Addiction Equity Act (MHPAEA) discussed further at slide 35.

Multi-Prong Approach to Prevention*

- Follow CDC Guidelines for proper prescribing
- Support use of state prescription drug monitoring programs
- Explore other treatment modalities first

- FWA programs evaluating use and shopping habits
- Simplify treatment referral process
- Prior Authorization/Quantity Limit programs
- Network evaluation/restrictions
- CDC guidelines

Regulatory

- Drug Time & Dosage Limits
- Doctor Shopping Laws
- Tamper-Resistant Rx Forms
- Rx Drug Identification Laws
- First fill state laws
- Overdose Emergency Immunity
- Consider ways to increase use of <u>Prescription Drug Monitoring Programs</u>, which are among the most promising statelevel interventions.

Regulatory Plan Sponsors

Prescriber

PBMs

Public

 Learn more about Opioids Awareness

- FWA programs evaluating use and shopping habits
- · Simplify treatment referral process
- Prior Authorization/Quantity Limit programs
- Network evaluation/restrictions
- CDC guidelines

^{*}Opioid management may raise considerations related to compliance with the Mental Health Parity and Addiction Equity Act (MHPAEA) discussed further at slide 34.

Thank You

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