Flexibility to Improve Care for Patients with OUD: Implementing SAMHSA's Changes to 42 CFR Part 8

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Family Guidance Centers, Inc.

- Federal and state licensed opioid treatment program
- 10 Locations:
  - Chicago North – 310 W. Chicago Ave. (Outpatient)
  - Chicago South – 2630 S. Wabash Ave. (Outpatient)
  - Chicago West – UI Health Mile Square Health Center (Outpatient)
  - Aurora (Outpatient)
  - Des Plaines (Outpatient)
  - Harvey (Outpatient)
  - Joliet (Outpatient)
  - Manteno (Outpatient and Residential)
  - Springfield (Outpatient and Residential)
  - Quincy (Outpatient)

Patients Served – SFY 2023	
310 W. Chicago	1,772
Aurora	494
Des Plaines	618
Harvey	424
Joliet	1,571
Manteno	812
Quincy	84
Springfield	1,245
UI Health-Mile Square	270
Wabash	1,694
Total	**8,984**

Medications for the Treatment of Opioid Use Disorder

What is Methadone?

Methadone is a synthetic *opioid agonist* that eliminates withdrawal symptoms and relieves drug cravings by acting on opioid receptors in the brain—the same receptors that other opioids such as heroin, morphine, and opioid pain medications activate.

Although it occupies and activates these opioid receptors, it does so more slowly than other opioids and, in an opioid-dependent person, treatment doses do not produce euphoria (“high”).

Methadone’s slower metabolism in the body makes it possible for patients to function normally, attend school or work, and participate in other forms of treatment or recovery support services to help them work towards long-term recovery.

Methadone Dosing

Methadone dosing should begin at a low dose and increase gradually with close monitoring over days or weeks. At stable daily doses, serum levels peak 2 to 4 hours after dosing, then slowly decrease, providing 24 hours without overmedication or withdrawal.

Overall, the methadone dosing protocol includes the following:

- The initial goal is to reduce opioid withdrawal and craving safely.
- Uses the “start low and go slow” approach but increases the dose at a rate that minimizes chances of continued opioid use, while monitoring for side effects.
- Increases the dose over initial weeks in program.
- Reaches an adequate/therapeutic dose that stops withdrawal symptoms for 24 hours, reduces or eliminates cravings, and blunts or blocks euphoria from self-administered other opioids.

In general, after induction is complete, higher doses are more effective than lower doses.

Clinical outcomes of MOUD vs treatment without medication

Outcome	Buprenorphine	Methadone	XR Naltrexone
Increased retention in treatment	X	X	X
Reduced illicit opioid use	X	X	X
Reduced risk of overdose death	X	X	
Reduced all-cause mortality	X	X	
Reduced HIV risk behaviors	X	X	

Source: SAMHSA Tip 63, 2020

Retention in Treatment at 12 Months With Reduced Illicit Drug Use

Treatment type	Retention in treatment at 12 months with reduced illicit drug use
Behavioral therapy without medication	6%
XR Naltrexone*#	10–31%
Buprenorphine*	60–90%
Methadone*	74–80%

https://www.chcf.org/wp-content/uploads/2017/12/PDF-Why-Health-Plans-Should-Go-to-the-MAT.pdf

Access to MOUD

Despite the overwhelming evidence demonstrating the effectiveness of the medications for the treatment of opioid use disorder, researchers found that in 2021, of the estimated 2.5 million people aged 18 and older with an opioid use disorder (OUD), only 1 in 5 of them (22%) received medications to treat it (Jones et al., 2021).

OTP Regulations - Methadone

1. The FDA oversees the manufacturing and labeling of methadone. They ensure the safety, effectiveness, and consistent quality that are applied to virtually all prescription drugs under the Federal Food, Drug, and Cosmetic Act.
2. Because methadone is a legal narcotic drug, its production, distribution, and dispensing are subject to the requirements applied to schedule II controlled substances by the Drug Enforcement Administration (DEA) to prevent diversion and illicit use.
3. In the case of methadone, a unique third tier of special standards has been established by SAMHSA prescribing how and under what circumstances methadone may be used to treat OUD. SAMHSA certification is dependent upon obtaining accreditation from an entity approved by SAMHSA to accredit OTPs.
4. State governments also have a separate level of regulations, including licensure and rules about OTP operations.

Increased Take Home Flexibility During COVID

- On March 16, 2020, SAMHSA issued an exemption to Opioid Treatment Programs (OTPs) whereby a state could request "a blanket exception for all stable patients in an OTP to receive up to 28 days of Take-Home doses." States could also request an exemption for an OTP to "request up to 14 days of Take-Home medication for those patients who are less stable but whom the OTP believes can safely handle this level of Take-Home medication."
- In the three years following the initial exemption, states, OTPs, and other stakeholders reported increased treatment engagement, improved patient satisfaction with care, with relatively few incidents of misuse or medication diversion. SAMHSA concluded that there was sufficient evidence that the exemption enhanced and encouraged use of OTP services at a time of significant fentanyl-related overdose mortality.
- SAMHSA published a Methadone Take-Home Flexibilities Extension Guidance in November 2021 and in April 2023, revising the standards applicable to OTP provision of methadone for unsupervised use. The April 2023 Guidance was effective until one year after the end of COVID PHE or until final changes to 42 CFR Part 8.

Take Home Dose Flexibilities

- In treatment 0-14 days, up to 7 unsupervised take-home doses of methadone may be provided to the patient
- Treatment days 15-30, up to 14 unsupervised take-home doses of methadone may be provided to the patient
- From 31 days in treatment, up to 28 unsupervised take-home doses of methadone may be provided to the patient

Telehealth Flexibilities During COVID

In April 2020, SAMHSA exempted OTPs from requirement for in-person physical examination for patients treated with buprenorphine, if adequate evaluation of the patient could be accomplished via telehealth (audio only or audio/visual). *This exemption did not include induction of methadone via telehealth technology.*

In May, 2023, SAMHSA issued guidance extending buprenorphine telehealth flexibilities for OTPs for one year past the end of COVID PHE or until final changes to 42 CFR Part 8.

Final changes to 42 CFR Part 8 made buprenorphine telehealth flexibilities permanent and *allows for the use of audio-visual telehealth for any new patient who will be treated by the OTP with methadone, if it is determined that an adequate evaluation of the patient can be accomplished via an audio-visual telehealth platform* (a full in-person physical examination must be completed within 14 calendar days).

Changes to 42 CFR Part 8 – Key Areas

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Accreditation and Certification: OTPs must obtain certification from the Substance Abuse and Mental Health Services Administration (SAMHSA) to dispense opioid agonist medications.

Patient Evaluation and Treatment: The regulations specify criteria for patient evaluation, admission, and ongoing treatment.

Dispensing of Medications: OTPs are authorized to dispense FDA-approved opioid agonist medications for the treatment of OUD, including methadone, buprenorphine, and naltrexone.

Compliance and Oversight: Compliance with federal regulations is monitored through regular inspections and oversight activities overseen by SAMHSA and other relevant agencies.

Flexibility and Telehealth: In response to evolving healthcare needs and public health emergencies such as the COVID-19 pandemic, the regulations allow for flexibility in treatment delivery

Underlying Values and Principles of the Revised Rule

Patient-centered care

Shared practitioner-patient decision-making

- Practitioners' clinical judgment
- Responsive, flexible OTP services
- Evidenced-based practice
- Non-stigmatizing language (ex. removes references to "detoxification" and "drug abuse")

Revised 42 CFR Part 8: Changes In How OTPs Deliver Care

SAMHSA finalized updates to 42 CFR Part 8, the federal rule that governs Opioid Treatment Programs (OTPs), in February 2024.

The effective date of the final rule was April 2, 2024, and the compliance date is October 2, 2024.

Makes all flexibilities allowed during COVID permanent

Removes all language and rules pertaining to DATA Waiver

The revised rule will enhance OTPs, improve collaboration with partner services and facilitate access to medications for opioid use disorder (MOUD).

Fostering trust and recovery in a patient-centered environment

- Allows eligibility for take-home doses upon entry into treatment
- Removes requirement of having at least a one year history of OUD for admission to OTP
- Removes participation in counseling as a contingency for medication access (shift from “Required Services” to “Shared Decision Making”).
- Continues to require the OTP to offer adequate treatment services to meet patient needs

Acknowledging the skill and understanding of practitioners

Includes NPs and PAs as practitioners able to order and manage methadone (Medical Director still must be a physician).

Includes the otential for medical screening by practitioners external to the OTP.

Accepts examination results of non-OTP practitioners, if the exam is verified by an OTP practitioner (e.g. MD, NP, or PA).

Total dose for the first day is now up to 50 mgs, unless the practitioner determines that a higher dose was clinically indicated and documents that in the patient's record.

Expanding Access to Care

Expands access through incorporation of telehealth and integration of care among OTPs:

- Initiation of methadone using audiovisual technology
- Initiation of buprenorphine through audio-only or audio-visual technology
- Remove participation in counseling as contingency for medication.
- Revises the language for toxicology testing from identifying misuse to a strengths-based approach, such as “allowing for extenuating circumstances”.
- Incorporates harm reduction and recovery principles. Allows for distribution of supplies that allow an individual to test their personal drug supply for adulteration with substances that increase the risk of overdose.
- Incorporates overdose education and distribution of opioid overdose reversal medications

Expanding Access to Care

Access expanded by:

- Expanding the range of services allowed in medication and mobile units
- Extending use of interim treatment from 120 to 180 days, if comprehensive services are not readily available in the area within 14 days. Requires moving patients from interim to comprehensive treatment during the interim period.
- Recognizing long-term care facilities and jails with DEA hospital/clinic registrations can dispense methadone when OUD is adjunct to a primary health condition
- Encouraging collaboration with other services

What does this mean for OTPs

Opportunity to:

- See more patients
- Improve retention in care
- Expand the reach of the OTP with mobile units
- Expand the reach of OTPs with medication units in other services
- Integrate primary care, infectious disease treatments, and mental health services

Implementation of Take Home Flexibilities at FGC

- System-wide training for all FGC staff began in June 2023
- Staff had questions regarding **missing bottles, continued positive toxicology results and early returns for additional doses**.
- Training stressed that an automatic change to daily supervised dosing (code change) is not agency policy. Documentation in EHR (SAMMS) outlining the circumstances should be reviewed and the treatment team should offer their recommendation to the FGC provider for a final determination. If take homes continue on existing schedule, additional resources such as video observation of methadone dosing (Sonara) can help support patients.

Video Observation of Methadone Dosing

As a way to support patients receiving take home methadone doses, video observation helps OTPs confirm adherence to take-home doses, potentially increasing the number of take-homes and subsequently reducing barriers to treatment, increasing retention in care, and reducing the risk of opioid overdose.

Video observed dosing is now possible through smartphone technologies, making it possible for patients to video-record themselves taking methadone at home and securely submit those videos to clinic staff for review.

FGC implemented a video observation pilot utilizing Sonara Health's remote medication monitoring system for a group of FGC patients who could benefit from a more flexible schedule of take-home doses. From March-August 2023, 122 FGC patients were enrolled in the Sonara pilot, with over two-thirds of these patients' methadone doses being successfully remotely observed during this time period.

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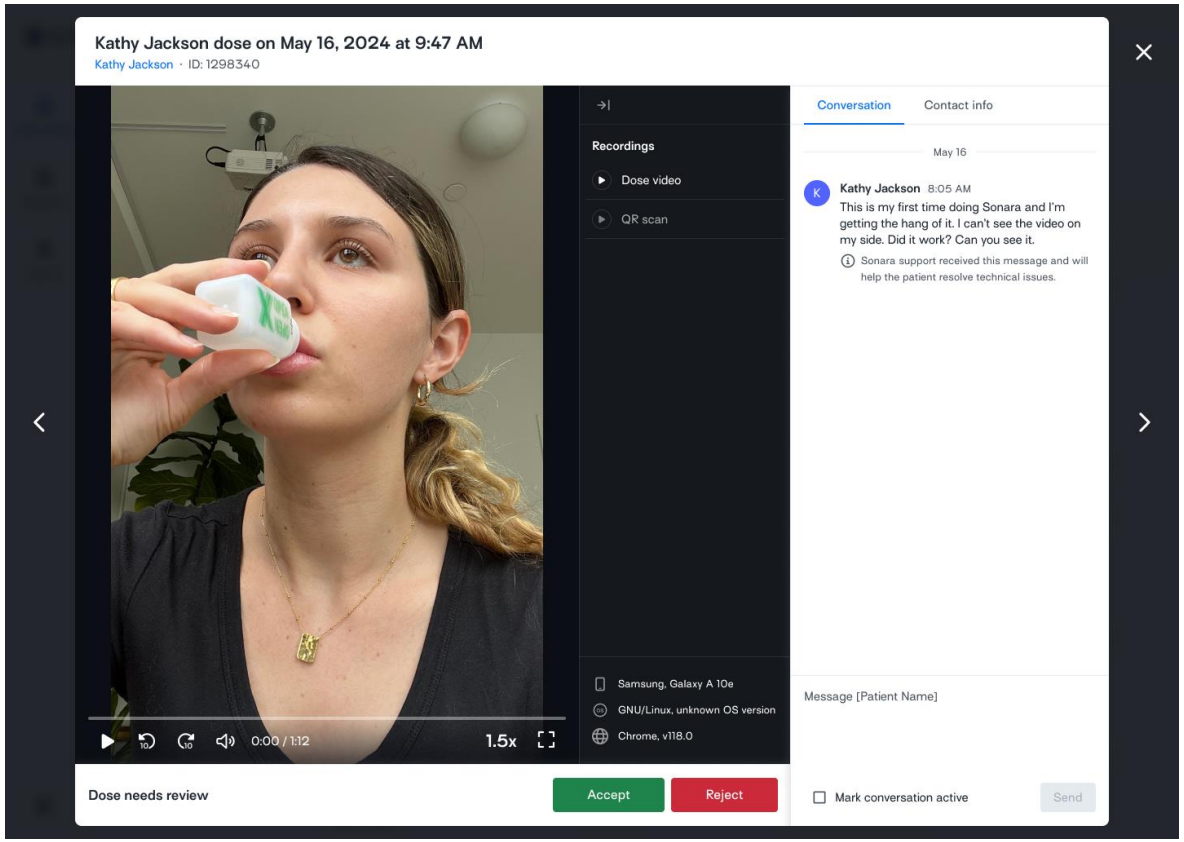


Video Observation of Methadone Dosing

During this pilot phase at FGC, a patient satisfaction survey was conducted with overwhelming positive feedback:

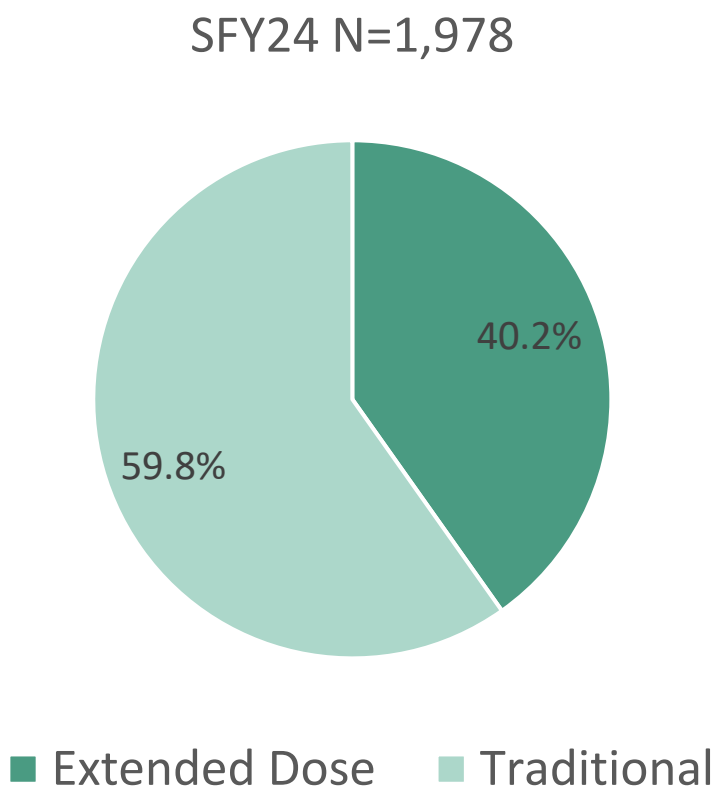
- 93% of patients who completed the Sonara Patient Satisfaction Survey expressed feeling very satisfied (78.6%) or somewhat satisfied (14.7%) with Sonara
- 95% of patients expressed benefiting from less travel time to the clinic
- 82% of patients reported more time for their family
- 79% of patients reported having more time for social activities
- 77% of patients reported improved mental health
- 64% of patients reported having more time for employment

Extended Dosing Implementation-FGC

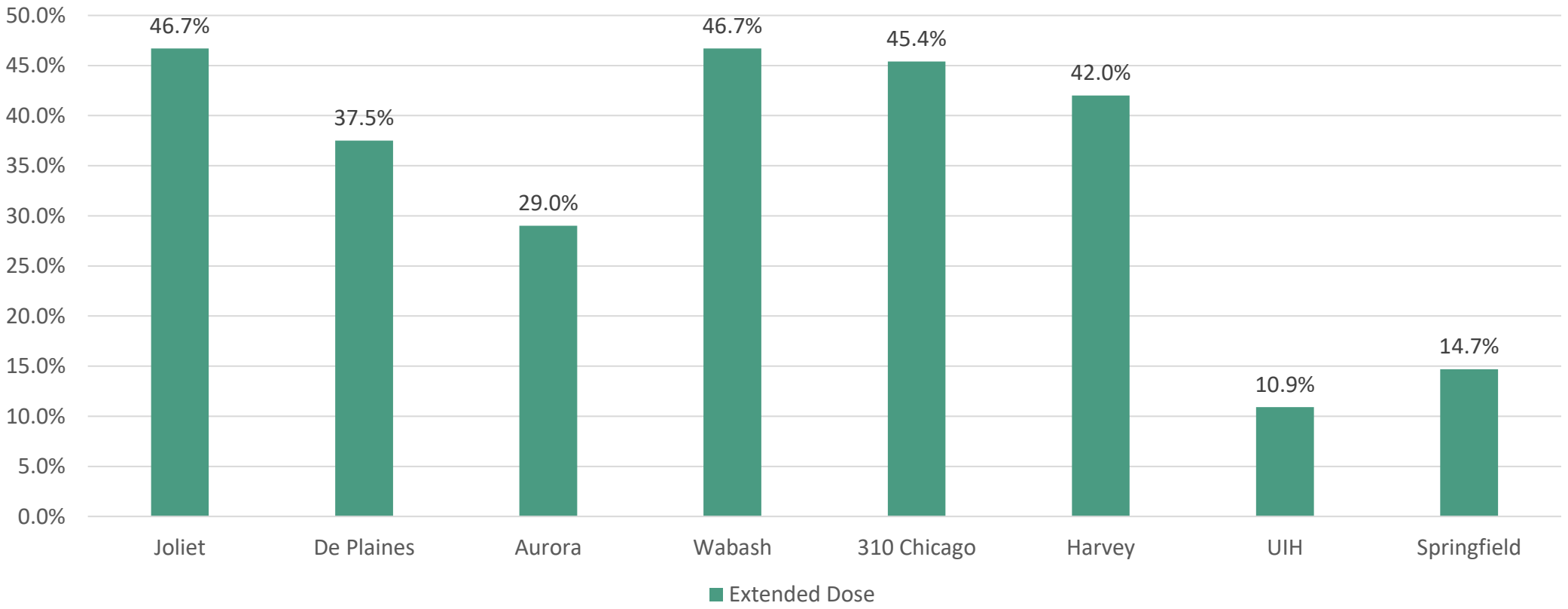
- Extended dosing began in July 2023
- Work flow process for patient admission (Day One) was overhauled to include an initial form documenting the following SAMHSA requirements:

1. Acute respiratory issues, cardiac contra indicators, unstable diabetes symptoms, hypertensive, suicidal ideation or active psychotic symptoms are not present at this initial examination physical examination.
2. ILPMP review, past history with previous FGC treatments and practitioner interview resulted in no adverse findings.
3. No evidence of concurrent active substance use disorder contraindications with methadone induction; commitment to active participation with FGC treatment planning process likely.
4. Naloxone (Narcan) education and supply was provided.
5. Transportation & storage safety plan was documented.

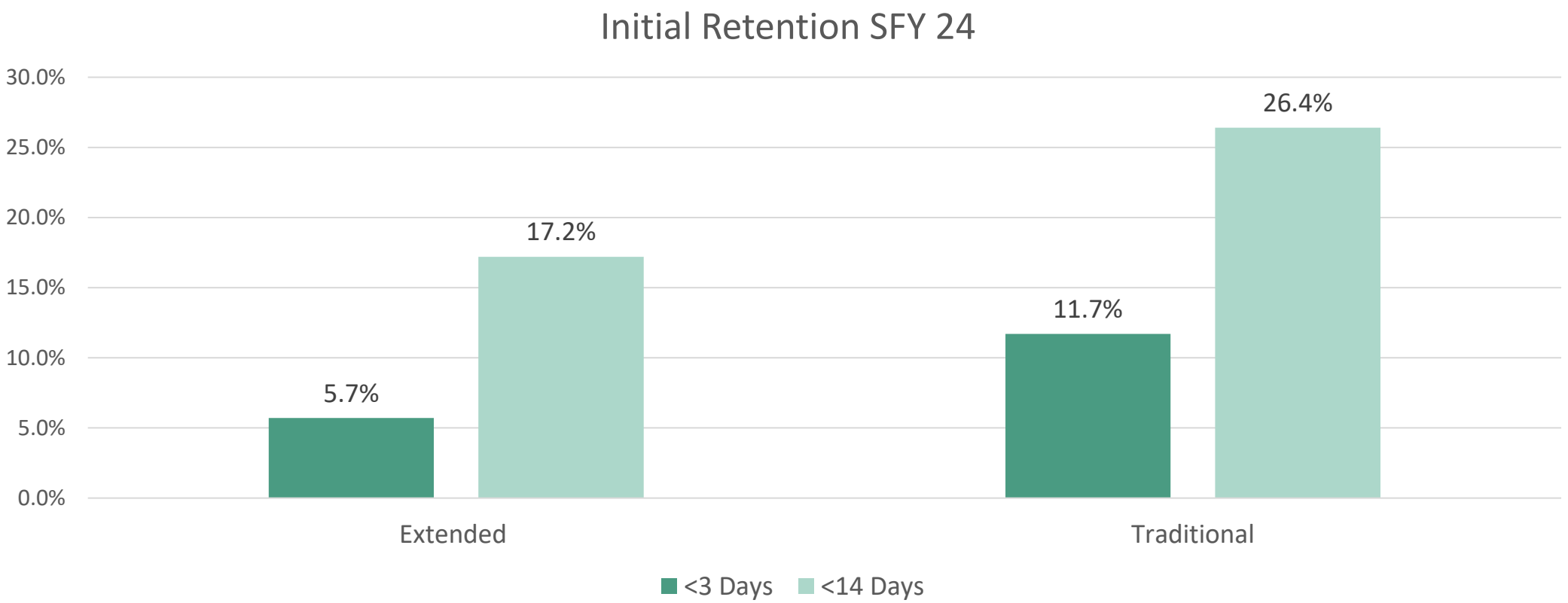
Extended Dosing at FGC



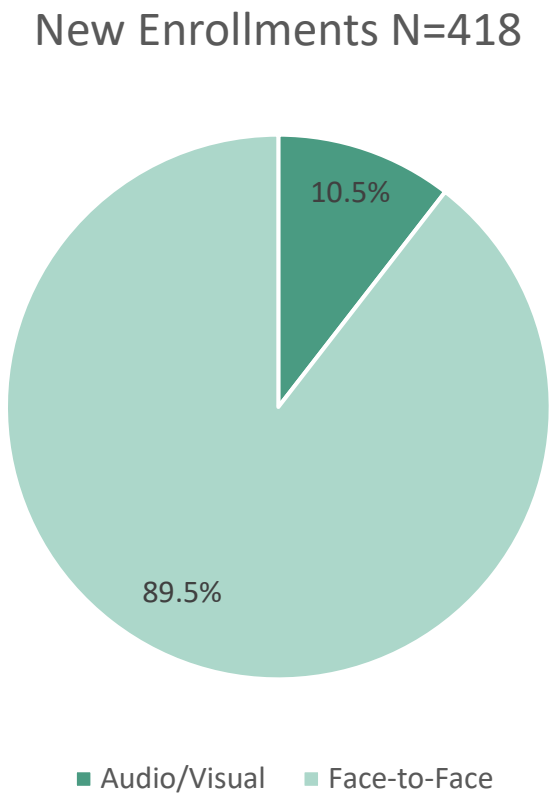
Extended Dosing by Site – SFY24



Extended Dosing and Retention



Two Way Audio/Visual Induction Pilot at FGC: March 2024-June 2024



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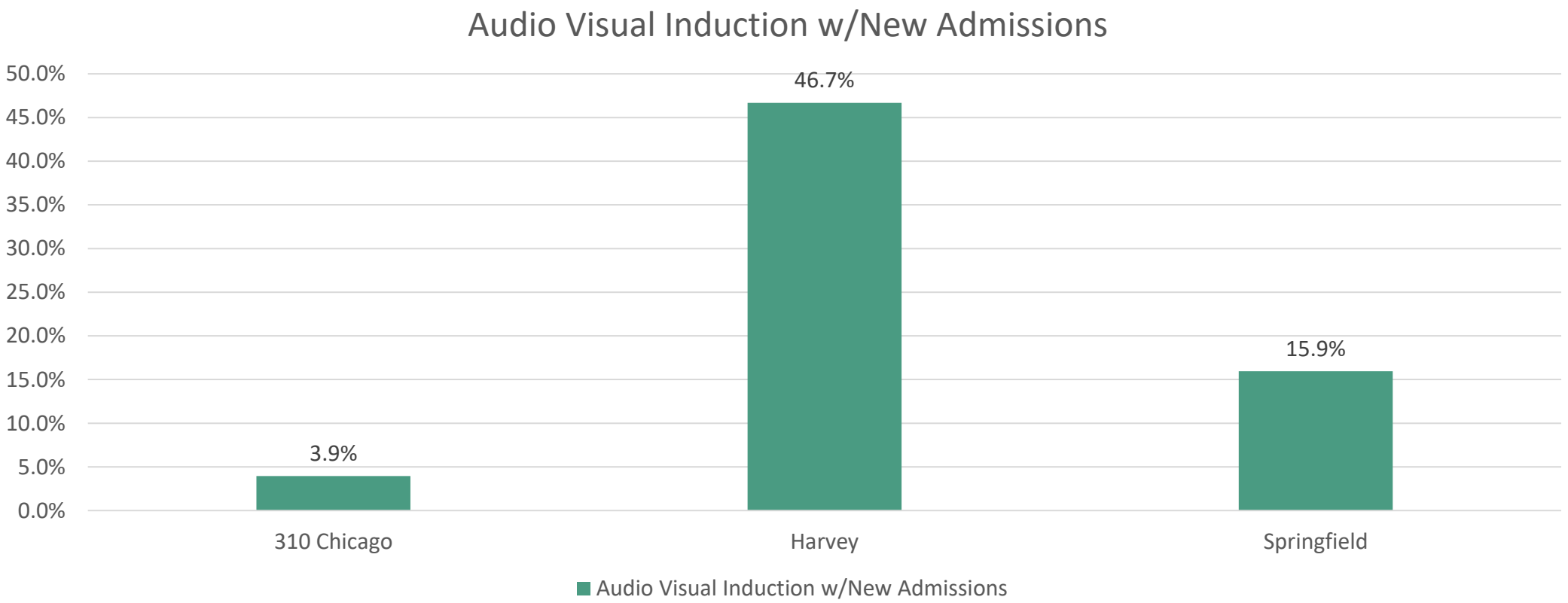

Initial Findings on Two Way Audio/Visual

- Two Way Audio/Visual is an important resource for clinics that have limited physician/prescriber hours for walk-ins.
- Initial data suggests lower 3 Day Drop-Out rates for those receiving 2 Way Audio/Visual (6.8%) vs. those receiving face-to-face evaluation (12.3%).
- Implementation requires coordination between front desk staff, nursing and physicians/prescribers at other locations.

Conclusions

- The revisions to 42 CFR Part 8 together hold great promise for improving the accessibility of medications for the treatment of OUD.
- Substantive, procedural, and linguistic changes promote a more patient-centered approach to treatment in OTPs.
- The new rule emphasizes the benefit of telehealth amid the evolving landscape of healthcare delivery for its ability to facilitate greater accessibility to treatment and align with the diverse needs and circumstances of patients seeking care for OUD.

Contact

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Questions?