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CMS LTC Survey Updates: Regulations and Guidance to Surveyors on Psychotropic Medication Use

Presented by:

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2025

New York State Survey Updates

Before we get into what's new…

Current Survey Trends

- **Controlled Substance Security, Handling and Documentation**
  - **Picked up during Med Pass Observation**
  - **Failure to sign incoming/outgoing**
  - **Handling of the keys**
  - **Failure to follow "Order of Operations": Sign out of narc count → administer → sign MAR**
- **Med Refrigerators with narc boxes**
  - **Refrigerator not secured to wall or floor***
  - **Internal box not double locked**
  - **Internal box contained d/c'd items**

New York State Survey Updates

Before we get into what's new (Part 2…)

Current Survey Trends

- **Insulin Pens (and other "Top Drawer" Items)**
  - **Failure to indicate start date**
  - **Past expiration date once opened**
- **Med Carts**
  - **Loose Pills on bottom of blisterpacks drawer**
  - **Cleanliness**
- **Follow-up on Drug Regimen Review**
  - **Last 6 months, 5 residents**
  - **Agree, or disagree and state reason**
- **PASRR Level 2 for Schizophrenia!**

CMS Psychotropics Survey Update

New CMS Guidance:

- **Issued November 18th, 2024**
  - **897 total pages initially – now 911 pages.**
  - **No "comment period", no warning.**
- **Implementation:**
  - ~~**February 24th, 2025**~~
  - ~~**March 24th, 2025**~~ **(with some additions, changes or clarifications)**
  - **April 28th, 2025 (with more additions, no changes or clarifications)**
  - **Located here:**
    - **https://www.cms.gov/files/document/qso-25-14-nh.pdf**

CMS Psychotropics Survey Update

All Regulations on the "Minimum Standards for Participation" and Guidance to Surveyors are published by CMS in the State Operations Manual (SOM)

- **The SOM is divided into chapters, called "F-Tags", each covering important elements to nursing home care and operations**
- **Psychotropics are (now) covered primarily in**
  - **F605: Physical and Chemical Restraints**
  - **F658: Comprehensive Care Plans**

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CMS Psychotropics Survey Update

Key Elements of the updated Guidance to Surveyors

- **Return to basics: Psychotropics as "Chemical Restraints" and "Use for Convenience of Staff"**
- **Clarifies the requirements for Non-Drug Interventions prior to initiating or increasing the dose of psychotropics**
- **Clarifies the requirements on Gradual Dose Reductions**
- **Includes NEW guidance requiring Consent prior to initiating or increasing the dose of psychotropics**
- **Adds NEW requirements for use of Schizophrenia as a diagnosis**
- **Adds NEW related element at F841: Medical Director**

CMS Psychotropics Survey Update

F605: Psychotropics as "Chemical Restraints" and "Use for Convenience of Staff"

- **All prior regulations on psychotropics and unnecessary drugs formerly found at F758 (Unnecessary Drugs) were relocated to F605.**
  - ***But Why?***
- **The regulation itself is unchanged – the Guidance to Surveyors has been nearly totally overhauled.**

F605: Psychotropic Drugs

§483.45(e) Psychotropic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that--

§483.45(e)(1) Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record;

§483.45(e)(2) Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;

§483.45(e)(3) Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and

§483.45(e)(4) PRN orders for psychotropic drugs are limited to 14 days. Except as provided in §483.45(e)(5), if the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident's medical record and indicate the duration for the PRN order.

§483.45(e)(5) PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.

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F605: Psychotropics as "Chemical Restraints"

Chemical Restraints: Convenience and Discipline

F605 specifies the following:

"Residents have the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms. Facilities are responsible for knowing the effects medications have on their residents. ***If a medication has a sedating or subduing effect on a resident and is not being administered to treat a medical symptom, the medication is acting as a chemical restraint.*** *These effects could indicate an intentional action to discipline or make care more convenient for staff. or the facility did not intend to sedate or subdue a resident, but an unnecessary medication is being administered that has that effect.*

Convenience *refers to the unnecessary administration of a medication that causes (intentionally or unintentionally) a change in a resident's behavior (e.g., sedation) such that the resident is subdued and/or requires less effort from staff. Therefore, if a medication causes symptoms consistent with sedation (e.g., excessive sleeping, drowsiness, withdrawal, decreased activity), it may take less effort to meet a resident's behavioral needs, which meets the definition of convenience.*

Discipline *refers to any action, such as the administration of a medication, taken by facility staff for the purpose of punishing or penalizing residents."*

F605: Psychotropics as "Chemical Restraints"

Potential Survey Targets

- **Low dose** antipsychotics, particularly if ordered for **"Agitation", "Restlessness and Agitation"; unspecified "Mood Disorder", or "Behaviors".**
- **Bedtime (HS)** doses of psychotropics
- Any medication used as a psychotropic at any dose that causes **excessive sedation or potential side effects such as falls**
- Any medication used as a psychotropic at any dose **when initiated *without an assessment of potential medical causes of the distress or behavior.***
- Any medication used as a psychotropic at any dose when initiated without adequate attempts at **non-pharmacologic interventions.**

F605: Psychotropics as "Chemical Restraints"

Examples of Recommended Dosage Range:

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Atypical Antipsychotic:	*FDA Approved Indication:*	*Recommended Daily Dose Range-Adults**
Olanzapine (Zyprexa)	• Treatment of Schizophrenia • Treatment of Bipolar I Disorder	• 10mg • 10-15mg
Quetiapine (Seroquel)	• Treatment of Schizophrenia • Treatment of Bipolar I Disorder • Adjunctive therapy for Major Depressive Disorder	• 150-750mg • 300-800mg • 150-300mg
Risperidone (Risperdal)	• Treatment of Schizophrenia • Treatment of Bipolar I Disorder	• 4-8mg • 1-6mg

What are we accomplishing with low dose antipsychotics, besides sedation?

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F605 Psychotropics: Non-Pharmacologic Interventions

F605 provides the following specific guidance to surveyors regarding non-drug interventions for behaviors:

> *"Psychotropic medications may be indicated if:*
> - *behavioral symptoms present a danger to the resident or others;*
> - *expressions or indications of distress that are significant distress to the resident;*
> - *if not clinically contraindicated,* ***multiple non-pharmacological approaches have been attempted, but did not relieve the medical symptoms which are presenting a danger or significant distress…****"*

F605 continues with this additional language:

> *"...if a resident is receiving a psychotropic medication, regardless of whether the medication is approved for the resident's condition,* ***there must be documentation that the facility has attempted behavioral (nonpharmacological) interventions****, and that these interventions have been deemed clinically contraindicated."*

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Non-Drug Intervention Log for Newly Emergent Behaviors

Documentation of Interventions prior to or in place of initiation of Psychoactive Medication Use

Instructions: This form is for use for new onset behaviors. In such cases, current practice standards call for the use of non-pharmacologic interventions prior to resorting to psychoactive medications. **Complete top two sections of this form prior**

Non Drug Interventions attempted:(Check all that apply)
☐ Resident taken to separate or quiet area and allowed opportunity express needs and/or for behaviors to resolve
☐ Redirection and verbal comfort provided
☐ Audio and/or Visual Stimulation provided (videos, music, television, radio)
☐ Modification of environmental stimuli (noise, temperature, lighting, etc.)
☐ Provide nourishment (Food, snacks, and fluids) as diet allows
☐ Bowel/Bladder: Constipation care; Toileting and/or Incontinence Care, if needed
☐ Medicated for Pain management, when indicated and so ordered
☐ Diversional Mobility (Assisted ambulation, Wheel Chair Propelling, etc.)
☐ Other Diversional Activities: _____

Interventions Effective? ____ **Yes***

____ ***No, Physician will be contacted, section below to be completed.***

*** (If Non-Drug Interventions are effective, NO FURTHER ACTION is necessary!)**

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F605 Psychotropics: Gradual Dose Reductions

Definition of "*Gradual Dose Reduction*":

"Gradual Dose Reduction (GDR)" is the stepwise tapering of a dose to determine if symptoms, conditions, or risks can be managed by a lower dose or if the dose or medication can be discontinued.

Gradual Dose Reduction Guidelines:

Within the first year in which a resident is admitted on a psychotropic medication or after the prescribing practitioner has initiated a psychotropic medication, the facility must attempt a GDR in two separate quarters (with at least one month between the attempts), ***unless clinically contraindicated***.

Definition of "*Clinically Contraindicated*":

For any individual who is receiving a psychotropic medication, a GDR may be considered clinically contraindicated for reasons that include, but that are not limited to, the following:

- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or exacerbate an underlying medical or psychiatric disorder; or

- The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or exacerbate an underlying medical or psychiatric disorder or increased distressed behavior.

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F605 Psychotropics: Gradual Dose Reductions

Gradual Dose Reduction DOCUMENTATION Requirements:

- Medical record documentation should reflect the date of the GDR attempt, the outcome of the dose reduction attempt, **and the plan regarding future GDR attempts**. *This documentation is* ***required*** *for ALL uses regardless of underlying diagnosis. T****his includes chronic enduring conditions such as schizophrenia, bipolar disorder, or adjunctive treatment for major depressive disorder.***/

- Physician documentation ***must contain the rationale for why GDR attempts are clinically contraindicated*** for the resident. Simply stating "GDR Clinically Contraindicated" is not enough.

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F605 Psychotropics: Consent for Initiation or Dose Increase

Consent and Resident's Right to be Informed

F605 very explicitly details the resident's rights as follows:

> *"...residents have the right to be informed of and participate in their treatment. Prior to initiating or increasing a psychotropic medication, the resident, family, and/or resident representative must be informed of the benefits, risks, and alternatives for the medication, including any black box warnings for antipsychotic medications, in advance of such initiation or increase.*
>
> *The resident has the right to accept or decline the initiation or increase of a psychotropic medication.*
>
> *To demonstrate compliance,* ***the resident's medical record must include documentation that the resident or resident representative was informed in advance*** *of the risks and benefits of the proposed care, the treatment alternatives or other options and was able to choose the option he or she preferred.*
>
> ***A written consent form may serve as evidence of a resident's consent to psychotropic medication, but other types of documentation are also acceptable.***"

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F658: Comprehensive Care Plans - Diagnosing Schizophrenia

Why is misuse of schizophrenia as a diagnosis an issue for CMS?

It's because of the

5 Star Quality Measures.

F658: Comprehensive Care Plans - Diagnosing Schizophrenia

The 5 Star Quality Measures

- ***Rankings of facilities on a wide variety of quality of care elements***
  - **Publicly posted on CMS "Nursing Home Compare" website**
    - **The higher number of stars, (theoretically) the better the care**
  - ***Drives referrals and reimbursement*, focuses survey attention on underperforming facilities**

F658: Comprehensive Care Plans Diagnosing Schizophrenia

Why the focus on misuse of this diagnosis?

- **CMS 5 Star Quality Measure for Antipsychotics (Long Stay) is calculated as follows:**

  "# of residents in house over 100 days on antipsychotics in the absence of schizophrenia"

- **Why exclude schizophrenia from the calculation?**
  - **CMS's attempt to not penalize facilities for taking in a *vastly underserved population***

F658: Comprehensive Care Plans Diagnosing Schizophrenia

The problem?

- **Misuse, intentional or not, erroneously improves a facility's 5 Star Quality Ratings**
  - **CMS believes misuse is rampant in all regions, and that *the misuse may be intentional.***

CMS's solution?

- **Implement *increased survey scrutiny and penalties* for misuse of the diagnosis**
  - **With TARGETED off-site audits; *and NOW***
  - **During "Annual" DOH Recertification Surveys**

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F658: Comprehensive Care Plans
Diagnosing Schizophrenia

F658 specifies the following:

Mental Disorders are diagnosed by a practitioner, using evidence-based criteria and professional standards, such as the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), and are supported by documentation in the resident's medical record.

***Examples of insufficient documentation** to support a mental health diagnosis would include:*

- *A situation where schizophrenia or another diagnosis is only mentioned as an indication in medication orders without supporting documentation.*
- *The addition of, or request by the facility to a practitioner for, a diagnosis of schizophrenia or another diagnosis without documentation supporting the diagnosis.*
- *A practitioner's note or transfer summary from a previous provider stating "history of schizophrenia," "schizophrenia," or another diagnosis without supporting documentation confirming the diagnosis with a previous practitioner or family, and the facility failed to provide evidence that a practitioner conducted a comprehensive evaluation after admission.*
- *A diagnosis list stating schizophrenia or another diagnosis without supporting documentation.*
- *A note of schizophrenia or another diagnosis in an electronic health record (EHR) without supporting documentation which populates throughout the EHR.*
- *A note of schizophrenia or another diagnosis in the medical record by a nurse without supporting documentation by the practitioner.*

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F658: Comprehensive Care Plans
Diagnosing Schizophrenia

Insufficient documentation for a new mental health diagnosis means that the resident's medical record does not contain the following:

- *Documentation (e.g., nurses' notes) indicating the resident has had symptoms, disturbances, or behaviors consistent with those listed in the **DSM criteria**, and for the period of time in accordance with the DSM criteria.*
- *Documentation from the diagnosing practitioner indicating that the diagnosis was given based on a comprehensive assessment, such as notes from a practitioner's visit.*
- *Documentation from the diagnosing practitioner indicating that the symptoms, disturbances, or behaviors are not attributable to (i.e., ruled out) the effects of a substance (e.g., a drug of abuse, a medication) or another medical condition (e.g., UTI or high ammonia levels).*
- *Documentation regarding the effect the disturbance is having on the resident's function, such as interpersonal relationships, or self-care, in comparison to their level of function prior to the onset of disturbance.*

The medical record must include documentation of ALL of these items, if not, this would constitute insufficient documentation.

F658: Comprehensive Care Plans
Diagnosing Schizophrenia

The current DSM-5 Standards for diagnosing schizophrenia are as follows:

DSM-5

(A) *Severe disturbance in sensory functioning and/or behavior*: Two (or more) of the following, each present for a significant portion of the time during a 1-month period (or less if successfully treated). At least one of these must be (1), (2), or (3):

(1) Delusions.

(2) Hallucinations.

(3) Disorganized speech (e.g., frequent derailment or incoherence).

(4) Grossly disorganized or catatonic behavior.

(5) Negative symptoms (i.e., diminished emotional expression or avolition)

(B) *Social/occupational dysfunction*: For a significant portion of the time since the onset of the disturbance, level of functioning in one or more major areas such as work, interpersonal relations, or self-care is markedly below the level achieved prior to the onset (or when the onset is in childhood or adolescence, there is failure to achieve expected level of interpersonal, academic, or occupational functioning).

(C) *Duration*: Continuous signs of the disturbance persist for at least 6 months. This 6-month period must include at least 1 month of symptoms (or less if successfully treated) that meet Criterion A (i.e., active-phase symptoms) and may include periods of prodromal or residual symptoms. During these prodromal or residual periods, the signs of the disturbance may be manifested by only negative symptoms or by two or more symptoms listed in Criterion A present in an attenuated form (e.g., odd beliefs, unusual perceptual experiences).

F658: Comprehensive Care Plans Diagnosing Schizophrenia

So what is the expectation?

This is the "Comprehensive Care Plan" F-Tag:

- **CCP meetings to update each resident's plan are held a minimum of quarterly.**
- **This infers a quarterly re-evaluation of the whether the Schizophrenia Dx given to a resident either by MDS coding at I6000 or in the text of the drug order(or both) is both accurate AND active!**
  - ***Minimum assessment by the TEAM quarterly!***

Schizophrenia

There's a difference between *having* schizophrenia and being able to *CODE* "Schizophrenia – I6000" on an MDS or claim as a diagnosis in a drug order!

- **Schizophrenia typically develops in someone's 20's or 30's, rarely later.**
- **Schizophrenia CAN**
  - **Burn Out**
  - **Be overwhelmed by other disease states. (Ex: Severe Dementia and other debilitating diseases)**
- **Have other causes of the behavior been ruled out? If not, CANNOT use the diagnosis!**
- **No treatment? Cannot code.**

F658: Diagnosing Schizophrenia

Common Question:

"What about residents who aren't currently exhibiting any symptoms?

- **How does true schizophrenia present itself?**
- **Is it possible to be completely controlled? Likely?**
- **How accurate is the assessment/documentation?**
- **Is schizophrenia burning out or being overwhelmed by other disease states?**
  - ***Should a GDR be considered? (Emphasis on the "G"!)***

- **This is ALL why schizophrenia assessment is now part of the CCP!**

F658: Diagnosing Schizophrenia

What Qualifies as an "Active Diagnosis"?

- **Treatment in the last 7 days (Medication)**
- **Documentation *in the medical record* of**
  - **symptoms consistent with professional standards for a Dx of Schizophrenia; AND**
  - **persisting for greater than 6 months; AND**
  - **Documentation that medical causes have been ruled out**
- **What are the "Professional Standards"?**
  - ***DSM-5 Criteria for Diagnosing Schizophrenia***
    - ***Detailed explicitly in F658!!***

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Schizophrenia: CCP Team Assessments

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Adding or Confirming a Schizophrenia Diagnosis

A Guide for Practitioners and MDS Coordinators

Resident Name _____ **Date of Evaluation** _____

*In order to diagnose **ACTIVE Schizophrenia** (or a schizophrenia-related diagnosis) and code on MDS at I6000, the following criteria must be met:*

Medical Workup Requirement for Schizophrenia and Schizophrenia-Related Diagnoses:

☐ A medical workup which has been documented in the medical record has determined that the disturbance is not attributable to the physiological effects of a substance (e.g., a drug of abuse, a medication) or another medical condition.

Date of medical workup progress note: _____

ACTIVE TREATMENT(S) (*May include:* Medication, Psychotherapy). *Note:* in the absence of ACTIVE TREATMENT, do NOT code I6000 Schizophrenia, as "History of" does not qualify.

☐ Active Meds/Treatments: _____

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Schizophrenia: CCP Team Assessments

<u>For Schizophrenia</u> ***(Check off all applicable):***

Two (or more) of the following **Major Criteria**, present for a significant portion of time during a 1-month period or less if successfully treated. At least one must be (1), (2), or (3):

- ☐ 1. Delusions. ***Describe:*** _____
- ☐ 2. Hallucinations. ***Describe:*** _____
- ☐ 3. Disorganized speech (e.g., frequent derailment or incoherence).
- ☐ 4. Grossly disorganized or catatonic behavior.
- ☐ 5. Negative symptoms. Describe: _____

☐ Schizoaffective disorder and depressive or bipolar disorder with psychotic features have been ruled out.

☐ Continuous signs of the disturbance persist for at least 6 months. ***Describe history or date of onset of symptoms:*** _____

_____

_____

Schizoaffective Disorder: ***(Check off appropriate Major Criteria, above.)***

☐ An uninterrupted period of illness during which there is a major mood episode (major depressive or manic) concurrent with the **Major Criteria** of the illness.

☐ Symptoms that meet criteria for a major mood episode are present for the majority of the total duration of the active and residual portions of the illness.

Schizophrenia

Considerations and Common Questions:

What if the resident comes in without a schizophrenia diagnosis, but several days into their long term stay it becomes clear that they likely have schizophrenia?

- ***DO NOT GIVE SCHIZOPHRENIA DIAGNOSIS OR CODE I6000 for (at least) 6 months!***
  - **Pick up as chronic psychosis and begin weekly behavioral notes, documenting DSM-5 criteria.**

Schizophrenia

Other Important Considerations:

Remember when writing notes to BE DESCRIPTIVE.

- **Individualized notes citing symptoms unique to each resident MUST be the rule.**
  - **"Cookie Cutter" notes are basically useless.**
- **Give examples of the types of delusions or hallucinations; reference rambling/incoherent speech content; speak to "negative symptoms" such as lack of self care, etc.**
  - **Speak to the DURATION that these symptoms have persisted, even if it's a reference to years or decades as reported by the family, referring institution, or the resident themselves!**
  - **But most important, make it PERSONAL to that resident!**
- **Remember that *if you cannot write this kind of note, then you CANNOT diagnose or code I600 Schizophrenia* as an ACTIVE diagnosis!**

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F841: Medical Director

New Guidance to Surveyors at F841:

Medical director responsibilities must include:

- *Implementation of resident care policies, such as ensuring physicians and other practitioners adhere to facility policies on diagnosing and prescribing medications and intervening with a health care practitioner regarding medical care that is inconsistent with current professional standards of care.*

New Guidance to Surveyors at F658:

CMS is aware of situations where residents are given a diagnois of schizophrenia without sufficient supporting documentation that meets the criteria in the current version of the DSM for diagnosing schizophrenia. For these situations, determine if non-compliance exists related to the practitioner not adhering to professional standards of *practice* for assessing and diagnosing a resident.

Clearly, CMS is drawing a link!

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Getting in (and Staying in!) Compliance

- **Leverage the information in your Consultant Pharmacist Reports**

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Metro NY Healthcare (Sample)
Psychoactive Medication Use
Monthly Gradual Dose Reduction Tracking

January, 2025

UNIT: 3rd Floor

The following residents had active orders for antipsychotics on the date(s) during which Medication Regimen review was performed for this unit in the month listed above.

CATEGORY: Antipsychotic

Resident/Rm#	Medication	Dx On Physicians Order	Status/Date
M**** , J***l / 315-B	Olanzapine 5mg QD	Dementia with Behaviors	New Admission and/or Start of Tracking / 12-05-24
P****, J**** / 306-A	Quetiapine 25mg HS	Insomnia, Agitation	New Admission and/or Start of Tracking / 11-05-24
Q****, J*** / 310-A	Olanzapine 2.5mg HS	Psychotic disorder	Dose Taper / 01-05-25
S****, M**** / 300-B	Risperidone 0.5mg HS	Schizophrenia	New Admission and/or Start of Tracking / 01-05-25

- **Review at every Pharmacy/Med Staff Meeting!**

Getting in (and Staying in!) Compliance

- **Leverage PointClickCare, Sigma, Matrix and other EMR reports!**
  - **Ex: "New Orders, Last 7 Days" in PCC may allow for auditing to insure Consent is properly documented**
  - **Ex: Sigma Reports very good at giving current duration and indication for use.**
- **Involve Psych, Physicians, and Extenders in the reviewing the data!**
  - **Make sure that key personnel are aware of and HAVE READ the F-Tags!**

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Questions and Answers

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