WEBINAR

Ensuring an Appropriate and Well-Managed Medication List

State Operations Manual (SOM) Revisions Related to Psychosocial Harm in Nursing Homes

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Thank you for joining us!

What to expect

- Session is being recorded for replay
- Listen-only mode during the presentation
- Submit questions via the Chat Panel Q & A sessions at the end
- The recording and slides will be shared

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Speaker

Shawn Brockman, RN, MBA
Director of Strategic Planning

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Learning Objectives

In this webinar, attendees will learn:

1. About the changes to F329 with the release of the updated State Operations Manual (SOM)
2. What surveyors are looking for
3. 5 Simple strategies to reduce deficiency risk
4. The role technology can play in reducing citation risk and protecting your reputation

Background

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Background – Requirements for Participation – Medicare

- Requirements for LTC facilities (42 CFR part 483, subpart B) are the foundation for the State Operations Manuals (SOM)
- They were first published in the Federal Register on February 2, 1989 (54 FR 5316)
- Last comprehensive review was 1991 and have only been revised for legislative change or the need to address specific issues
- Significant change in service requirements and delivery techniques during that time not reflected
- This legislation drives the survey and F-tag process used in health inspections in the five star process (public reporting)

https://www.federalregister.gov/documents/2016/10/04/2016-23503/medicare-and-medicaid-programs-reform-of-requirements-for-long-term-care-facilities

Background on F-329

- Both a current and historical problem
- Nursing Home Data Compendium 2015 shows F-329 remained in the top 10 deficiencies since 2006, ranked 6th or higher
- 2-4% of total deficiencies within each year
- March 1, 2016 CASPER showed that based on the last standard health survey, 1/5 facilities were cited an F-329 deficiency
- Renewed look at antipsychotic use post focussed dementia care survey pilot project

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Downloads/nursinghomedatacompendium_508-2015.pdf

http://www.mcknights.com/marketplace/f-tag-in-focus-f-329/article/569295/

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Top Ten Deficiencies 2005 – 2014

Table 2.16. Ten Most Frequently Cited Health Deficiencies, 2005–2014

Deficiency Description	Tag #	Average Ranking	Rank (% of Citations) for Year									
			2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Store, cook, and serve food in a safe and clean way.	F0371	1.8	1 (5.1)	1 (4.9)	2 (4.8)	2 (5.0)	2 (5.1)	2 (5.5)	2 (5.6)	2 (5.8)	2 (6.1)	2 (6.2)
Ensure that a nursing home area is free from accident hazards and provide adequate supervision to prevent avoidable accidents.	F0323	2.4	4 (3.4)	2 (4.0)	1 (5.0)	1 (5.3)	1 (5.3)	3 (5.1)	3 (5.2)	3 (5.3)	3 (5.1)	3 (5.2)
Provide necessary care and services to maintain or improve the highest well-being of each resident .	F0309	3.6	2 (4.3)	3 (3.9)	3 (3.9)	4 (3.8)	4 (4.0)	4 (4.1)	4 (4.2)	4 (4.4)	4 (4.2)	4 (4.3)
Have a program that investigates, controls and keeps infection from spreading.	F0441	4.6	8 (2.5)	8 (2.5)	10 (2.4)	9 (2.6)	6 (3.4)	1 (5.7)	1 (6.4)	1 (6.6)	1 (6.4)	1 (6.7)
Develop a complete care plan that meets all the resident's needs, with timetables and actions that can be measured.	F0279	5.8	7 (2.8)	7 (2.7)	5 (3.0)	5 (3.2)	5 (3.4)	6 (3.5)	5 (3.6)	5 (3.6)	6 (3.6)	7 (3.4)
Ensure services provided by the nursing facility meet professional standards of quality.	F0281	6.1	3 (3.8)	4 (3.7)	4 (3.7)	3 (3.9)	3 (4.1)	5 (4.0)	8 (2.7)	10 (2.5)	10 (2.5)	11 (2.3)
Ensure that each resident's 1) entire drug/medication regimen is free from unnecessary drugs; and 2) is managed and monitored to achieve highest level of well-being.	F0329	8.3	18 (1.8)	15 (1.8)	8 (2.6)	6 (2.7)	7 (2.9)	7 (3.1)	6 (3.2)	6 (3.3)	5 (4.2)	5 (3.8)
Provide housekeeping and maintenance services.	F0253	8.8	6 (3.1)	6 (3.0)	6 (2.6)	7 (2.7)	8 (2.6)	8 (2.6)	11 (2.5)	11 (2.4)	12 (2.3)	13 (2.2)
Provide care for residents in a way that maintains or improves their dignity and respect in full recognition of their individuality.	F0241	10.0	10 (2.4)	12 (2.3)	12 (2.2)	12 (2.2)	12 (2.3)	9 (2.6)	9 (2.6)	8 (2.8)	8 (2.8)	8 (2.6)
Keep accurate, complete and organized clinical records on each resident that meet professional standards.	F0514	10.0	11 (2.3)	11 (2.4)	11 (2.3)	11 (2.5)	9 (2.4)	10 (2.5)	10 (2.6)	9 (2.6)	9 (2.6)	9 (2.6)
Give residents proper treatment to prevent new bed (pressure) sores or heal existing bed sores.	F0314	11.1	9 (2.5)	9 (2.5)	9 (2.6)	10 (2.5)	11 (2.4)	13 (2.3)	12 (2.4)	12 (2.3)	14 (2.2)	12 (2.3)

Nursing Home Data Compendium 2015 Page 146

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Downloads/nursinghomedatacompendium_508-2015.pdf

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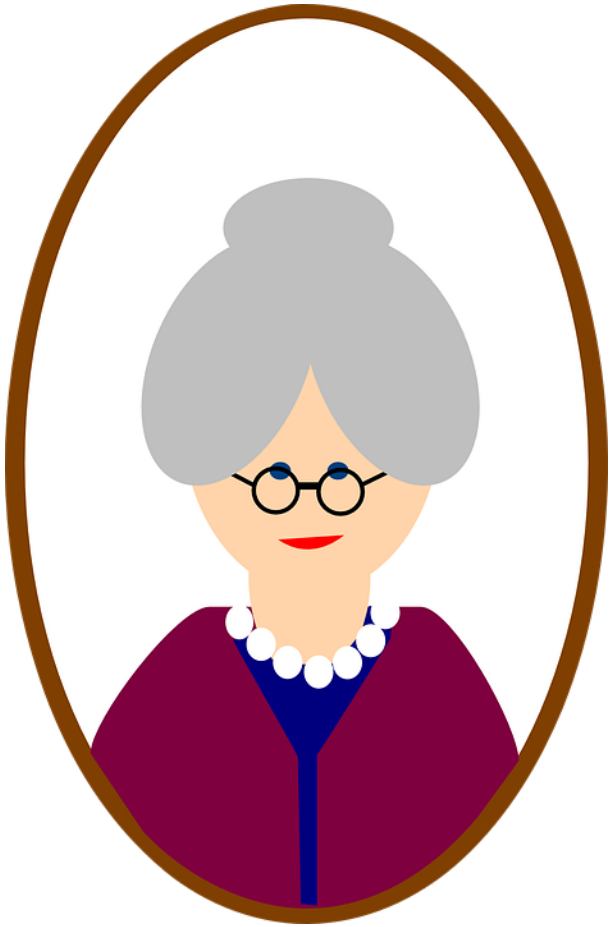
Background – Elderly LTC Residents

- Multiple Co-morbidities leading to complex medical regimes
- Physiological changes – poor excretion, impaired metabolism
- Increase number of **Geriatric Syndromes** present on admission increasing risk:
  - cognitive impairment, delirium, falls, reduced appetite, weight loss, urinary incontinence, delirium, pain, pressure ulcers, immobility, depression and polypharmacy



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Geriatric Syndromes

- 1 or more syndromes were prevalent in more than 90% of hospitalized adults referred to SNFs; 55% met criteria for three or more coexisting syndromes.
- The most-prevalent syndromes were falls (39%), incontinence (39%), loss of appetite (37%), and weight loss (33%).
- In individuals with 3 or more syndromes, the most common triad clusters were **nutritional syndromes (weight loss, loss of appetite), incontinence, and depression**.
- Treating hospital physicians commonly did not recognize and document geriatric syndromes in discharge summaries, missing 1/3rd to 95% of syndromes present.

https://www.ncbi.nlm.nih.gov/pubmed/27059831

https://www.ncbi.nlm.nih.gov/pubmed?term=27255830

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Geriatric Syndromes

- Patients were discharged to SNFs with an average of **14** medications, with an average of **5.9** medications that could lead to geriatric syndromes, with falls having the most associated medications at discharge at **5.5**
- Over 40% of all medications ordered upon discharge to SNFs were associated with geriatric syndromes
- On average, participants had 2.9 syndromes that persisted across both care settings, 1.4 syndromes that resolved, and 0.7 new syndromes that developed between hospital and SNF discharge
- Antiepileptics were associated with all syndromes, whereas antipsychotics, antidepressants, antiparkinsonism, and opioid agonists were associated with 5 geriatric syndromes
- Pharmacotherapy may be contributing to geriatric syndromes in this population

https://www.ncbi.nlm.nih.gov/pubmed/27590032 - Medications Associated with Geriatric Syndromes and their prevalence in older hospitalized adults discharged to SNFs.

What you Need to Know about the Update to the SOM for F-329

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New State Operations Manual

- https://www.federalregister.gov/documents/2016/10/04/2016-23503/medicare-and-medicaid-programs-reform-of-requirements-for-long-term-care-facilities
- https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-07.pdf
- https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-15.pdf
- Three Phases to SOM Updates
  - Phase I, November 28, 2016
  - Phase II, November 28, 2017
  - Phase III in November 29, 2019
- Changes to F329 occur in phases I and II

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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Changes to F-329

- Moved from Quality of Care Category to Pharmacy Services
- Expanded focus on psychosocial harm from medications
- Section on Psychotropic drugs added to F-329 that will take effect in Phase II
- Change in language from using the term Antipsychotic to the term Psychotropic drugs
- Psychotropic drugs are any drug that affects brain activities associated with mental processes and behavior

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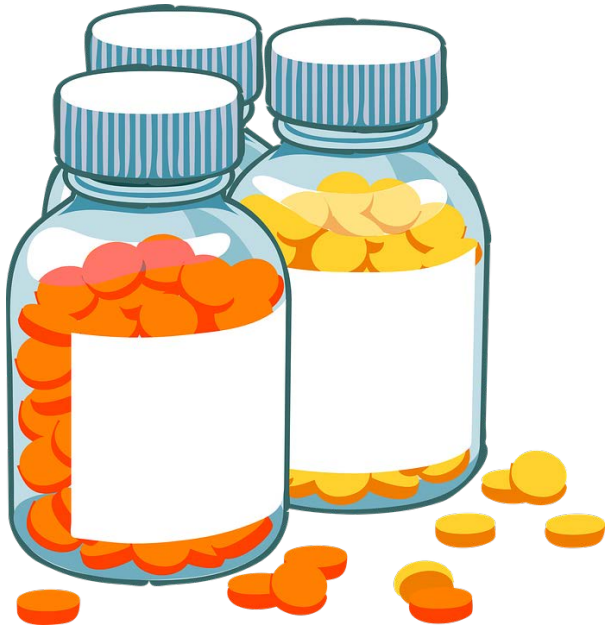
F-329 Requirements – November 28th, 2016

Part I- §483.45(d) Unnecessary Drugs—General

The unnecessary medication requirement has six aspects in order to ensure that medication therapy is appropriate for the individual resident.

The facility must assure that medication therapy (including antipsychotic agents) is based upon:

1. Appropriate Dose (including duplicate therapy)
2. Appropriate duration of use
3. Appropriate monitoring for efficacy and presence of adverse consequences
4. Diagnosis/Indication for Use
5. Reduction of dose or discontinuation if adverse consequences occur
6. Any combination of the above



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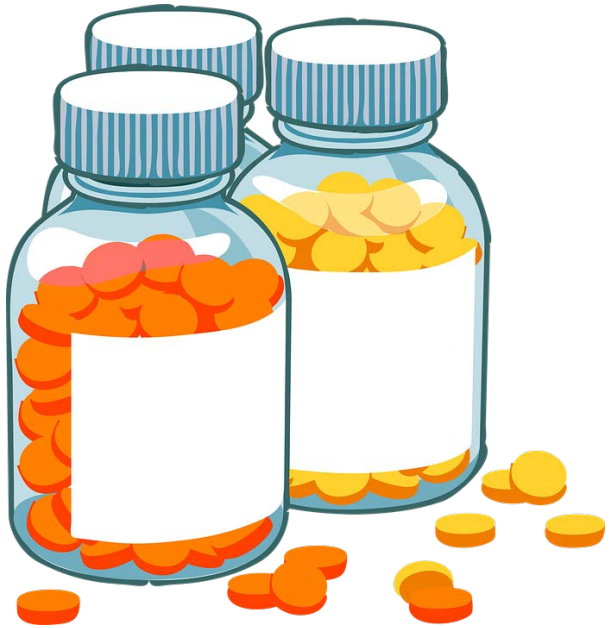
F-329 Requirements – November 28th, 2017

Part II-§483.45(e) Psychotropic Drugs

Based upon a comprehensive assessment of the residents, the facility must ensure, in addition to Part I requirements, that:

1. Residents not on psychotropic drugs are not given these drugs unless it is necessary to treat a specific documented condition
2. Residents on psychotropic drugs receive gradual dose reductions, and behavioral interventions, in an effort to discontinue these drugs
3. Residents don't receive PRN psychotropic drugs unless that medication is necessary to treat a specific documented condition
4. PRN orders for psychotropic drugs are limited to 14 days UNLESS the physician or practitioner believes and documents that the PRN order be extended beyond 14 days
5. PRN orders for anti-psychotic drugs are limited to 14 days and **cannot** be renewed unless the physician or practitioner evaluates the resident for the appropriateness of that medication and documents



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F-329 Intent – relatively unchanged

"…each resident's entire drug/medication regimen be managed and monitored to achieve the following goals:

- The medication regimen helps promote or maintain the resident's highest practicable mental, physical, and psychosocial well-being, as identified by the resident and/or representative(s) in collaboration with the attending physician and facility staff;
- Each resident receives only those medications, in doses and for the duration clinically indicated to treat the resident's assessed condition(s);
- Non-pharmacological interventions (such as behavioral interventions) are considered and used when indicated, instead of, or in addition to, medication;
- Clinically significant adverse consequences are minimized; and
- The potential contribution of the medication regimen to an unanticipated decline or newly emerging or worsening symptom is recognized and evaluated, and the regimen is modified when appropriate."

Surveyor Guidance – what you need to know for F-329

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It always starts with a Memo….

Memorandum Summary (March 2016 draft – Update November 2016)

- **F329 Draft Revision:** The Centers for Medicare & Medicaid Services (CMS) has revised guidance to surveyors in Appendix PP of the SOM under F329 to enhance ease of use for surveyors and to include language related to how unnecessary use of medications may cause psychosocial harm to residents.
- **Psychosocial Outcome Severity Guide:** CMS has revised language in the Psychosocial Outcome Severity Guide in Appendix P of the SOM.
- **Revisions to Selected F tags:** CMS has added language to selected F tags to emphasize the risk of psychosocial harm associated with noncompliance with specific regulations.
- The regulatory language remains unchanged.

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-15.pdf

Focus on Psychosocial Harm

Psychosocial Harm Revisions

The CMS has revised guidance at F329 in Appendix PP. Revisions include:

- Removing medication tables to make F329 easier to use.
- Replacing medication tables with up-to-date medication resources.
- Revising Deficiency Categorization examples to show that noncompliance at F329 can cause significant psychosocial harm.

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Focus on Psychosocial Harm

Revisions to guidance in the State Operations Manual issued in 2016 highlight the importance of reducing the risk of psychosocial harm associated with noncompliance with specific regulations. Recommendations include:

- Using non-pharmacological approaches for distressed behaviors
- Focusing on identifying underlying causes of delirium, a common adverse consequence from medications, as well as other factors such as electrolyte imbalance and infection
- Monitoring of psychosocial functioning that can result from a medication side effect
- Watching for signs, symptoms or conditions that may be associated with medications, such as apathy, lethargy, and mental status changes

http://www.mcknights.com/marketplace/f-tag-in-focus-f-329/article/569295/

Additional Guidance

Moreover, significant additions to the guidance noted in the deficiency categorization section of F329 include:

- Failure to recognize that symptoms of increased confusion and that newly developed inability to do activities of daily living resulting in hospitalization are the result of excessive doses of antipsychotic given without adequate clinical indication
- Failure to recognize the continuation of an antipsychotic, originally prescribed for delirium, has caused significant changes in the resident's behavior from baseline
- Failure to re-evaluate continuation of an antipsychotic originally prescribed for acute delirium which resulted in significant side effects

http://www.mcknights.com/marketplace/f-tag-in-focus-f-329/article/569295/

Compliance with F329

To ensure compliance with F329, a surveyor will seek to determine:

1. That a resident's meds address assessed needs and:
   - Are clinically indicated
   - Are in the best dose for the person
   - Administered for the right duration
2. That non-pharmacological approaches were attempted when clinically indicated
3. That gradual dose reductions were made for antipsychotics when and where appropriate
4. That care plans reflect appropriate monitoring parameters for medications or medication combinations that pose a risk of adverse effects
5. That a facility's medication management system monitors the effectiveness of medications and evaluates worsening signs or symptoms or change in condition that could be related to the medication
6. Whether the pharmacist performs monthly medication regimen reviews

http://www.mcknights.com/marketplace/f-tag-in-focus-f-329/article/569295/

5 Strategies for Preventing Tags at F329

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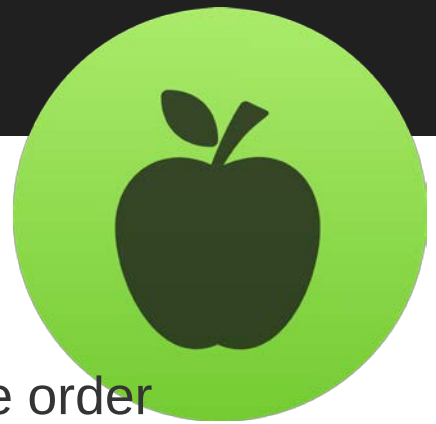
1. Education



- Ensure staff understand the definitions and intent of F-329
- Educate staff as to the requirements when receiving orders:
  - Indication for Use is mandatory, must be in the chart and appropriate to the order
  - Behavioural interventions come first and must be documented when carried out
  - End dates/Durations on PRN Psychotropic Orders are required
  - Evaluations by the PRACTITIONER are required before reorders/renewals are received.
  - How to recognize adverse effects
  - Documentation on care plans of meds and potential geriatric syndromes to look for
  - Black Box warning on all Psychotropics since 2006
  - Monthly Medication and Chart Reviews
- Need to understand the rationale for all psychopharmacological meds and why there may be dose changes or medication changes.

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2. Collaboration

- Clinical Practice Guidelines
- Team approach to care – including family/resident
- Develop an in-house team to look at psychotropic use routinely
- In-house expertise (additionally trained nurse for non pharmacological behavioural interventions)
- Determine pathways for discussion and timelines to promote timely feedback for changes to regimes
- Ongoing process with team communication for anyone on psychotropic and complex drugs

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3. Consultation

- Know and use your resources
  - Consulting pharmacist
  - Nurse Practitioner
  - Psychogeriatric teams
- CMS advises surveyors to speak with the consultant pharmacist and/or the prescriber when reviewing antipsychotic medication use for elderly residents with dementia.
  - Primary source of information of all medications for residents diagnosed with dementia
  - Provides better understanding of reasons for using or gradually reducing psychotropic
  - Coordinates with the team, to ensure the lowest possible dose required to improve symptoms and well-being.

http://www.pharmscript.com/cms-updates-guidelines-for-f329-unnecessary-drugs/

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4. Reconciliation

Medication reconciliation

- Formal process where healthcare providers work together with residents, families and care providers to ensure accurate and comprehensive medication information is communicated consistently across transitions of care
- Requires a systematic and comprehensive review of all the medications a resident is taking
- Ensures that medications being added, changed or discontinued are carefully evaluated against a comprehensive history.
- Important component of medication management and informs and enables prescribers to make the best prescribing decisions for the person.

https://www.ismp-canada.org/medrec/

4. Reconciliation

Best Possible Medication History (BPMH)

- Comprehensive medication history created using:
  1) a systematic process of interviewing the patient/family
  2) a review of at least one other reliable source of information to obtain and verify all of a patient's medication use (prescribed and non-prescribed).
- Complete documentation includes drug name, dosage, route and frequency.
- more comprehensive than a routine primary medication history

https://www.ismp-canada.org/medrec/

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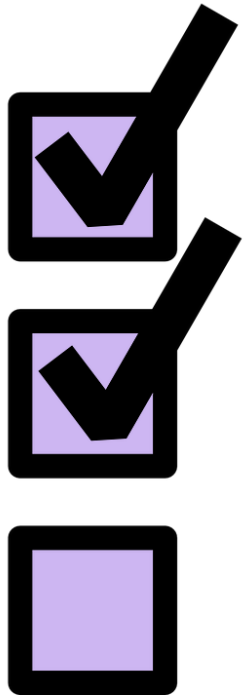
5. Evaluation

- Don’t assume – KNOW
- Audits should be routine and ongoing
- Team can be assigned to review all high risk medications (Tylenol, Psychotropic, Opioids, Anti-coagulants, IVs, Antibiotics, PPIs etc.)
- Look for missing information:
  - Indication for use
  - Dose/Duration
  - Evaluations/Documentation
  - Comprehensive Assessments
  - Routine Monitoring
  - Capture of adverse effects and resulting treatment changes
- Action Findings and record changes and progress



Technology

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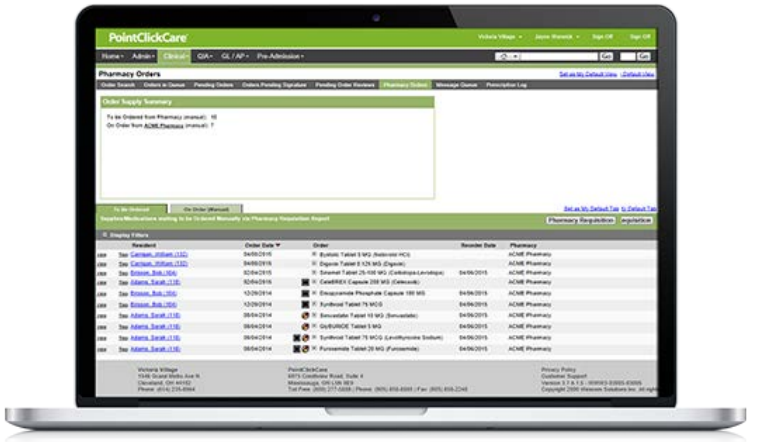
Solutions through Technology

- Medication Management Systems with Decision Support
  - Prevent documentation lapses with medication ordering and administration
- Point of Care applications
  - Track behavioural interventions and monitoring for side effects
- Ability to Communicate with practitioners securely
  - HIPAA protection while promoting better and more timely communication
- Mobile Physician and Practitioner Access to the EHR
  - Mobile access to charts for better decision making

Medication Management Systems

- Closed Loop Medication systems that work within the EHR
- Medication Management – eMAR
  - Force compliance on orders
  - Standardize processes
  - Don’t allow missed documentation
  - Prompt for assessment of vitals where necessary
  - Alert to interactions and duplicate therapies
  - Black-box warnings
  - High risk medication alerts and processes
  - Simplify auditing and process evaluation



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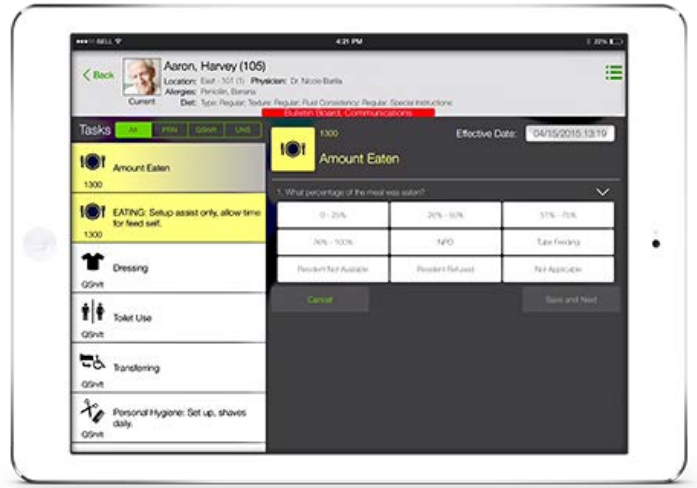
Point of Care

- Capture changes in condition that may result from medication changes or additions
  - Geriatric Syndromes: cognitive impairment, delirium, falls, reduced appetite, weight loss, urinary incontinence, delirium, pain, pressure ulcers, immobility, depression
- Improved monitoring for side effects reporting by bedside care givers
- Documentation of non-pharmacological behavioural interventions, mood and behaviour capture and response
- Routine vitals for medication administration



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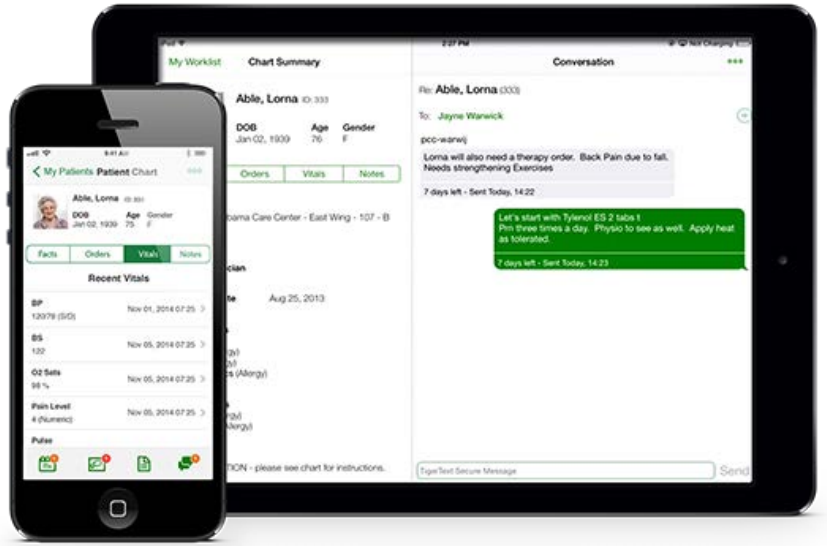
Secure Texting

- HIPAA secure texting – staff are doing it regardless of the security of the device.
- Apps ensure HIPAA and health care compliance – can be embedded in EHR
- Allows real time communication without being “on the phone”
- Improves response times by hours
- Allows conversion of text to progress notes when decision making results from collaboration
- Should link practitioner apps to nursing home EHR



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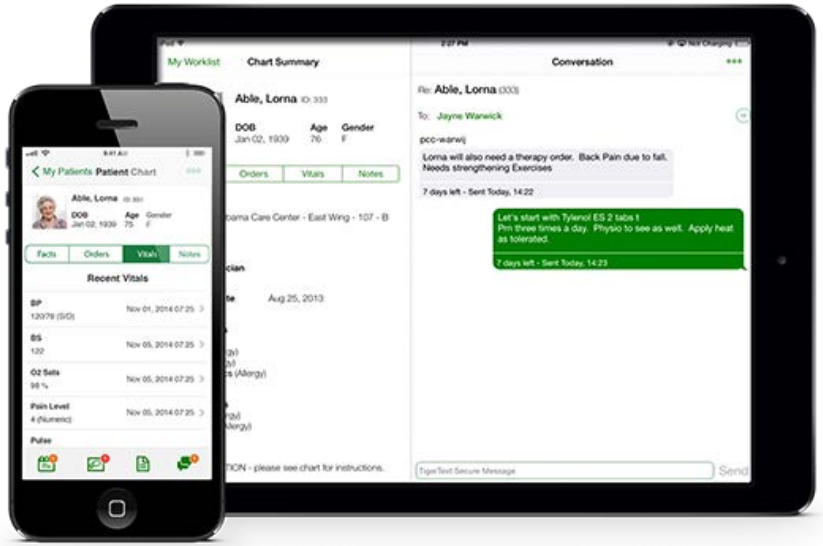
Mobile Practitioner Engagement Solutions

- Improves connectivity and response times with doctors and other practitioners through mobile connectivity
- Allows communication and documentation remotely
- Allows viewing of relevant chart information for better and more timely decision making without relying on someone else to interpret and communicate the data
- Decision support
- Links to billing for MD purposes
- Improves collaboration and resident care



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Conclusions

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Eliminate F-329 from your top 10!!

- Make sure you are clear on the new requirements and their compliance dates
- Ensure staff understand and are complying with requirements – they carry the mantle of responsibility in knowing what care is required and being provided and why for any individual
- Use your resources to help you with compliance – Consulting pharmacists, NP in general medication management issues; Behavioral consultants, Alternative Therapies for non-pharmacological interventions
- Have processes in place for monitoring your own compliance
  - Always room for improvement
  - Make it a team sport
  - Care Team as a whole needs to address behavioral interventions
- Use technology to your advantage

Questions?

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We’d love to hear from you!

Please take a moment to fill out our brief survey.

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Thank you for joining us!

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http://www.medicareadvocacy.org/examining-inappropriate-use-of-antipsychotic-drugs-part-one-how-seven-states-cite-antipsychotic-drug-deficiencies/ Authors -Toby S. Edelman, Dean Lerner, June 27, 2013

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https://www.ismp-canada.org/lmssa/ (Audit)

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J Am Geriatr Soc. 2016 Oct;64(10):2027-2034. doi: 10.1111/jgs.14320. Epub 2016 Sep 2. **Stability of Geriatric Syndromes in Hospitalized Medicare Beneficiaries Discharged to Skilled Nursing Facilities.** Simmons SF, Bell S, Saraf AA, Coelho CS, Long EA, Jacobsen JM, Schnelle JF, Vasilevskis EE.

Medication Resources Replacing Medication Tables

- *MedlinePlus,* https://www.nlm.nih.gov/medlineplus/druginformation.html
- *National Library of Medicine Drug Information Portal,* http://druginfo.nlm.nih.gov/drugportal/drug/categories.
- *The Food and Drug Administration (FDA) webpage, Medwatch: The FDA Safety Information and Adverse Event Reporting Program , http://www.fda.gov/Safety/MedWatch/default.htm*
- *GlobalRPh Drug Reference, http://globalrph.com/drug-A.htm*
- *The TakeRX website's generic drug prefix and suffix list, http://www.takerx.com/class.html*
- *The DrugLib.com Index of Drugs by Category, http://www.druglib.com/drugindex/category/*
- *The University of Maryland Medical Center Drug Interaction Tool, http://umm.edu/health/medical/drug-interaction-tool*

Symptoms, Signs, And Conditions That May Be Associated with Medications

- Behavioral changes, unusual behavior patterns (including increased distressed behavior*, social isolation or withdrawal*)
- Bleeding or bruising, spontaneous or unexplained
- Bowel dysfunction including diarrhea, constipation and impaction
- Dehydration, fluid/electrolyte imbalance
- Depression, mood disturbance
- Dysphagia, swallowing difficulty
- Falls, dizziness, or evidence of impaired coordination
- Gastrointestinal bleeding
- Headaches, muscle pain, generalized or nonspecific aching or pain
- *Lethargy*
- Mental status changes, (e.g., new or worsening confusion, new cognitive decline, worsening of dementia (including delirium*), inability to concentrate)*
- *Psychomotor agitation (e.g., restlessness, inability to sit still, pacing, hand-wringing, or pulling or rubbing of the skin, clothing, or other objects).*
- *Psychomotor retardation (e.g., slowed speech, thinking, and body movements)*
- Rash, pruritus
- Respiratory difficulty or changes
- Sedation (excessive), insomnia, or sleep disturbance
- Seizure activity
- Urinary retention or incontinence

Guidelines for Indications for Use in Psychotropic Drugs

INAPPROPRIATE

- Wandering
- Poor self-care
- Restlessness
- Impaired memory
- Mild anxiety
- Insomnia
- Inattention or indifference to surroundings
- Sadness or crying alone that is not related to depression or other psychiatric disorders
- Fidgeting
- Nervousness
- Uncooperativeness such as refusal or difficulty receiving care

When the preceding indications are present in combination with the following criteria, CMS states a **resident with dementia may be appropriate for the use of an psychotropic medication**:

- Behavioral symptoms present a danger to the resident and others.
- AND one OR both of the following are present:
- Symptoms are identified as being due to mania or psychosis.
- *AND/OR*
- Behavioral interventions have been attempted and included in the plan of care, except in an emergency.

http://www.pharmscript.com/cms-updates-guidelines-for-f329-unnecessary-drugs/

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Side Effects Antipsychotics

- General – anticholinergic effects, falls, excessive sedations
- Cardiovascular – cardiac arrhythmias, orthostatic hypotension
- Metabolic – increase in total cholesterol and triglycerides, unstable or poorly controlled blood sugar, weight gain
- Neurologic – akathisia, neuroleptic malignant syndrome, Parkinsonism, tardive dyskinesia, cerebrovascular events (strokes or transient ischemic attacks.)