

White Paper on  
Chemical Restraint Use  
*for*  
*The California Department of Public Health*

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<b>1. Introduction and Background .....</b>	<b>1-1</b>
Introduction .....	1-1
Background on Chemical Restraints .....	1-1
Regulatory Overview .....	1-2
<b>2. Analysis of Chemical Restraints as a Quality Measure .....</b>	<b>2-1</b>
Developing a Chemical Restraint Use Measure .....	2-2
<b>3. Recommendations on Chemical Restraint as a Quality Measure .....</b>	<b>3-1</b>
Conclusions .....	3-1
Recommendations and Next Steps .....	3-1
<b>4. Potential Use of Antipsychotic Drug Use as a Quality Measure .....</b>	<b>4-1</b>
Alternative Medication-Related Performance Measure .....	4-1
Overview .....	4-1
Existing Performance Measure .....	4-3
Summary .....	4-5
<b>5. Conclusions .....</b>	<b>5-1</b>
<b>6. Appendix A. MDS 3.0 Measure Specifications .....</b>	<b>6-1</b>

### Introduction

The California legislation AB 19, which was passed in June of 2011, requires the California Department of Public Health (CDPH) and the California Department of Health Care Services (DHCS) to implement a Skilled Nursing Facility (SNF) Quality and Accountability Program (QAP) and to consider incorporating additional performance measures including a measure on the use of chemical restraints.

CDPH contracted with Health Services Advisory Group, Inc. of California (HSAG) to develop a white paper that addresses the issue of chemical restraints quality measurement. The purpose of this white paper is to review the state of chemical restraints quality measurement and to determine if a chemical restraint measure can be included in the QAP. DHCS in collaboration with CDPH will examine the recommendations.

### Background on Chemical Restraints

The concept of chemical restraints, as described in psychiatric, acute care, and emergency department literature, refers to the use of medications to control behavior such as delirium, agitation, violent behaviors, or unplanned extubation.<sup>1-1,1-2,1-3</sup> Medications used as chemical restraints include sedatives and analgesics, antipsychotics (typical and atypical), or a combination of both.

However, behavioral experts disagree on the use of the term chemical restraint. A survey of experts conducted for the Expert Consensus Guidelines on Behavioral Emergencies showed that the majority of the experts believed that “medications used to treat specific psychiatric diagnoses should be considered treatment measures rather than restraints, even in the absence of provisional diagnosis.”<sup>1-4</sup>

Chemical restraints issues fall under the larger category of quality of care issues associated with medication use in general. These issues include but are not limited to:

- ◆ Was the medication prescribed for a Food and Drug Administration (FDA) indicated condition?
- ◆ Was the medication prescribed appropriately for off-label use?

<sup>1-1</sup> Currier, G. W.(2003). The Controversy over “Chemical Restraint” in Acute Care Psychiatry. *Journal of Psychiatric Practice*, 9(1).

<sup>1-2</sup> Hofso, K. & Coyer, F. M. (2007). Chemical and Physical Restraints in the Management of Mechanically Ventilated Patients in the ICU: Contributing Factors. *Intensive and Critical Care Nursing*, 23.

<sup>1-3</sup> Rossi, J, Swan, M. & Isaacs, E. D. (2010). The Violent or Agitated Patient. *Emergency Medicine Clinics of North America*, 28(1). 235-256.

<sup>1-4</sup> Currier, G. W.(2003). The Controversy over “Chemical Restraint” in Acute Care Psychiatry. *Journal of Psychiatric Practice*, 9(1).

- ◆ Was the medication prescribed in appropriate dosage and duration, and was there continuous monitoring of adverse effects?

Additionally, there are issues surrounding the concept of chemical restraints that remain unresolved, including, but not limited to the following:<sup>1-5</sup>

- ◆ Are chemical restraints ever appropriate?
- ◆ If so, what are the reasonable thresholds for the appropriate use of chemical restraint medications?

## Regulatory Overview

The Centers for Medicare & Medicaid Services (CMS) uses different guidelines and definition for chemical restraint. The Omnibus Budget Reconciliation Act (OBRA) of 1987 mandated that residents be free from physical or chemical restraints imposed for the purposes of discipline or convenience. OBRA states that restraints may only be used to ensure physical safety of the resident or other residents and only upon the written order of a physician that specifies the duration and circumstances under which the restraints are to be used.

In addition, OBRA of 1987 required the regulation of certain drugs in nursing homes and limited the use of PRN (or as needed) medication orders and required efforts to withdraw the drug or decrease the dosage for residents receiving psychotropic drugs. Further, the OBRA of 1990 mandated the regulation of certain drugs used in nursing homes and the establishment of a drug utilization program in nursing homes. This mandate refocused the role of the pharmacist in becoming an active participant in reducing potential drug therapy problems in nursing homes.

To implement the requirements of OBRA of 1987, CMS implemented survey and enforcement procedures outlined in the State Operations Manual (SOM) Appendix PP Guidance to Surveyors for Long Term Care Facilities. The SOM provides the following definitions related to chemical restraints:<sup>1-6</sup>

- ◆ **Chemical Restraints**—refers to any drug that is used for discipline or convenience and not required to treat medical symptoms.
- ◆ **Discipline**—refers to any action taken by the facility for the purpose of punishing or penalizing residents.
- ◆ **Convenience**—refers to any action taken by the facility to control a resident’s behavior or manage a resident’s behavior with a lesser amount of effort by the facility and not in the resident’s best interest.
- ◆ **Medical Symptom**—denotes an indication or characteristic of a physical or psychological condition.

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<sup>1-5</sup> Ibid.

<sup>1-6</sup> CMS. State Operations Manual (Internet-only Manual), Pub. 100-07, Appendix PP Guidance to Surveyors for Long Term Care Facilities, F222, §483.13(a) Restraints.

The CMS SOM further stipulates that medical symptoms that warrant the use of restraints must be documented in the medical record, assessments, and care plans. Although a physician's order may reflect the presence of a medical symptom, the facility is ultimately accountable for the appropriateness of that determination. In essence, a physician's order alone is not sufficient justification for the use of restraints.

## 2. ANALYSIS OF CHEMICAL RESTRAINTS AS A QUALITY MEASURE

### Overview

In order to evaluate chemical restraint use as a potential measure in the QAP, HSAG conducted an environmental scan to identify the prevalence rate among nursing homes and to determine if performance measures exist to evaluate this area of care.

### Environmental Scan Findings

#### *Prevalence Rate*

HSAG conducted a comprehensive literature review to determine the prevalence rate of chemical restraint use. However, HSAG did not find any data on chemical restraints prevalence in California nursing homes. Similarly, HSAG did not find current published rates on F222 deficiencies issued by California State surveyors. Tag number F222 corresponds to deficiencies related to inappropriate chemical restraints. Survey deficiencies, such as F222, are collected and reported in the Online Survey and Certification and Reporting System (OSCAR). Further, HSAG scanned the list of deficiencies published on the Nursing Home Compare Web site for California nursing homes and did not find any deficiencies related to chemical restraints.

However, there is widespread local media coverage on chemical restraints allegations citing both anecdotes on inappropriate drug use and CMS data on antipsychotic use in nursing homes.<sup>2-1,2-2</sup> Most anecdotes cited in the media used the term chemical restraints and inappropriate use of antipsychotic drugs interchangeably. While these two concepts overlap to some extent, there are differences. The term chemical restraint is narrower in concept since it focuses only on the use of drugs for convenience and/or discipline. Inappropriate antipsychotic drug use on the other hand, focuses not only on the inappropriate use, but also on drug dosage, duration, adverse effects monitoring, duplicative drug therapy, and other quality of care issues. In addition, chemical restraints include drugs other than antipsychotics, such as analgesics and sedatives.

#### *Existing Quality Measures*

HSAG searched publicly available quality measures databases such as the National Quality Forum (NQF) database and National Quality Measures Clearinghouse, as well as various States' nursing home quality and/or public reporting programs, but did not find any quality measure focused on chemical restraints as an indicator of quality. There are no existing quality measures on chemical restraints available for implementation in the QAP.

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<sup>2-1</sup> Chawkins, S. (2009). 3 Arrests in nursing home deaths in Lake Isabella. Los Angeles Times. <http://articles.latimes.com/2009>.

<sup>2-2</sup> Kiskan, T. (2011). Use of chemical restraints in nursing homes called an epidemic. Ventura County Star. <http://www.vcstar.com/news/2011>.

## Conclusions

Insufficient data on chemical restraint use in nursing homes makes it challenging to determine the existing prevalence. In addition, there are no existing quality measures to assess chemical restraint use; therefore, a measure would need to be developed.

## Developing a Chemical Restraint Use Measure

As previously mentioned, if a performance measure on chemical restraint use is to be implemented, a measure would need to be developed. However, there are significant challenges facing future development of a valid and reliable quality measure for chemical restraints. In order to develop a measure on chemical restraints, there must be a readily available data source from which valid and reliable information can be extracted. Information on whether drugs are given to a resident for the purpose of discipline and convenience, as opposed to treating medical symptoms, would be a required data element for a chemical restraints measure. A chemical restraints measure must be able to capture this data element from a valid and reliable data source. The two main methodological issues with developing a chemical restraint use measure are discussed below.

### Data Source

One of the main challenges in developing a quality measure for chemical restraints is finding a feasible data source to support data collection for the measure. Data sources provide data elements needed to compute measure scores. A chemical restraints measure would require a data source that combines or links information regarding a particular medication received by a resident and the rationale or indication for that medication.

HSAG evaluated potential data sources that can be used to extract data elements for a chemical restraints quality measure. However, all potential data sources reviewed posed significant limitations in their ability to support a chemical restraint quality measure.

**Minimum Data Set (MDS).** A significant limitation of MDS is that it does not capture all medications given to a resident to support a chemical restraints measure. Section N of the MDS is limited to a resident's receipt of any antipsychotics, antianxiety, antidepressants, hypnotics, anticoagulants, antibiotics, and diuretics. However, medications such as sedatives, analgesics, and other drugs with similar effects also are used as chemical restraints.<sup>2-3</sup> These types of medications are not recorded in the MDS. In addition, the MDS does not provide any information on the rationale or indication for a medication.

**Part D Claims.** Part D claims data does not have adequate information to support the data elements required for a chemical restraints measure since diagnosis information is not a required data element on pharmacy billing transactions, nor is it generally included in prescriptions. Further, Part D claims do not capture dosage and drug indication that would specify whether the medication is used inappropriately.

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<sup>2-3</sup> Hofso, K. & Coyer, F. M. (2007). Part 1. Chemical and Physical Restraints Used in the Management of Mechanically Ventilated Patients in the ICU: Contributing Factors. *Intensive and Critical Care Nursing*, 23. 249-255.

**OSCAR Database.** Regulatory compliance deficiencies regarding chemical restraints (i.e., F222) are collected and reported by State surveyors in the OSCAR system, a computerized national database that is compiled and maintained by CMS. Although a chemical restraints measure derived from the OSCAR database seems achievable, studies have found that there are variations in surveyors' determinations of regulatory compliance that contribute to the reliability and validity issues of the OSCAR database.<sup>2-4,2-5</sup> As such, the OSCAR is a poor data source from which to derive a chemical restraints measure for a payment incentive program.

**Medical Records.** Certain medications are being prescribed for off-label use and there is some evidence that off-label use of these medications may be appropriate and not used as chemical restraints.<sup>2-6</sup> The medical record is potentially a data source from which the rationale for a medication received by the resident can be abstracted. However, there are several limitations related to abstracting chemical restraints events using medical records data (discussed in the next section) that make medical records inadequate for abstracting a chemical restraints measure.

### **Defining Observable Events**

In order to capture the concept of an outcome and measure aspects of that outcome, observable events must be defined.<sup>2-7</sup> For example, a chemical restraints event can be measured through health care encounters as documented in the medical record. However the criterion for what constitutes a chemical restraint needs precise definition. If a chemical restraint measure uses CMS' definition, identification of a chemical restraint event depends on medical record documentation of a medication being given to control behavior for discipline and/or convenience of the staff. Even if specific definitions of "discipline and/or convenience" can be established, these events cannot be easily determined through medical record reviews since information on whether drugs were used for discipline or convenience will most likely not be explicitly documented by clinicians in a medical record. Clinical judgment of whether the drug was used appropriately or not will usually be required in order to identify an instance of chemical restraint. This will lead to lack of standardization in abstracting information from the medical record, which will in turn decrease the reliability and validity of the measure.

### **Findings Regarding Data Sources**

Data derived from the MDS, OSCAR system, and Part D claims have severe limitations in capturing data elements required to calculate a chemical restraints measure score. As a possibility, a chemical restraints measure can be developed using data abstracted through medical record review alone or in conjunction with Part D claims data. However, this method of data collection is

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<sup>2-4</sup> Dellefield, M. (1999). Predictors of quality of care in California nursing homes. Dissertation Abstracts International (UMI No. 9943785), 60-08B, 3848.

<sup>2-5</sup> Harrington, C., Zimmerman, D., Karon, S., Robinson, J., & Beutel, P. (2000). Nursing home staffing and its relationship to deficiencies. *Journal of Gerontology: Social Sciences*, 55B(5), S278-S287.

<sup>2-6</sup> "Off-label" Use of Antipsychotic Drugs for Some Conditions Not Supported by Evidence. Press Release, September 27, 2011. Agency for Healthcare Research and Quality, Rockville, MD.  
<http://www.ahrq.gov/news/press/pr2011/ehcofflabelpr.htm>

<sup>2-7</sup> Agency for Healthcare Research and Quality. (2011). Quality Indicator Measure Development, Implementation, Maintenance, and Retirement. U.S. Department of Health and Human Service, Rockville, MD.  
<http://www.qualityindicators.ahrq.gov>

very costly to both the State and nursing homes. Further, if the data were to be abstracted by nursing home facility personnel, specific data abstraction algorithms need to be developed and training programs will have to be made available to ensure that data elements are collected uniformly across all facilities. Nursing homes may need to hire additional staff responsible for abstraction of chart data. Subsequently, the State will need to validate abstracted data to ensure accuracy.

### 3. RECOMMENDATIONS ON CHEMICAL RESTRAINT AS A QUALITY MEASURE

#### Conclusions

Based on the findings of the environmental scan, HSAG concluded there are no existing performance measures to assess chemical restraint use. In order to measure chemical restraint use, a measure would need to be developed and the measure would be focused on capturing whether drugs are given to a resident for discipline and convenience, and not required to treat medical symptoms. However, it is not currently possible to construct a valid and reliable measure on chemical restraints at this time for two main reasons. First, the MDS instrument, OSCAR system, and claims data do not provide the necessary data elements to construct a quality measure. These databases provide neither information on drug indications nor information on whether drugs are given for discipline or convenience. Medical record abstraction would be necessary in order to capture these required data elements. However, using medical record abstraction is resource intensive for both CDPH and the nursing homes.

Second, if medical record abstraction is to be done, it is still fraught with difficulty because the clinicians are unlikely to document that the medication was prescribed for discipline and/or convenience. Clinical judgment will be required for each record abstraction, which will result in lack of standardization (clinical judgment can vary) and will negatively impact the reliability and comparability of the measure results.

#### Recommendations and Next Steps

In view of the above barriers to developing a quality measure for chemical restraints, HSAG recommends looking into a measure related to medication quality of care issues: the inappropriate use of antipsychotic drugs. The potential adoption of this measure is discussed in more detail in section 4 of this document.

## 4. POTENTIAL USE OF ANTIPSYCHOTIC DRUG USE AS A QUALITY MEASURE

### Alternative Medication-Related Performance Measure

Measures related to medication quality of care issues exist, and could be adopted. Although it is not a substitute for measuring chemical restraints, inappropriate use of antipsychotic drugs is a measure that evaluates medication quality of care issues. This section provides an overview of the antipsychotic drug use performance measure for potential inclusion in the QAP.

### Overview

In general, an antipsychotic drug use measure is different from a chemical restraint measure. It is not focused on capturing events related to discipline and/or convenience. Nevertheless, it is an important indicator to capture because there have been instances in which use of these medications was found to be non-compliant with the CMS nursing home guidelines in the use of these drugs. One study found that over half of Medicare nursing home residents who received antipsychotics took doses that exceed maximum levels, received duplicative therapy, or had inappropriate indications according to the guidelines.<sup>4-1</sup> Additionally, CMS implemented regulations that residents who have not previously used antipsychotic drugs should not be given these drugs unless necessary to treat a specific condition as diagnosed and documented in the medical record.<sup>4-2</sup> CMS defines unnecessary drugs as those that are used in excessive dose, for excessive duration, without adequate monitoring, without adequate indications, and/or in the presence of adverse consequences that indicate that the dosage should be discontinued. CMS regulations also established antipsychotic dosing restrictions and listed medications considered potentially dangerous to the elderly.

### Off-Label Use

Off-label use of antipsychotic drugs occurs in nursing homes. Off-label use is defined as the use of an approved drug for treatment of conditions that are not included in the product's approval labeling or statement of intended uses.<sup>4-3</sup> The FDA allows off-label use of medications beyond those formally indicated and evaluated by the manufacturer. Although using drugs for off-label use offers innovative use of medications in clinical practice, it sometimes raises concerns about patient safety and cost.<sup>4-4</sup> Off-label use of an antipsychotic medication does not imply that it is being used as a chemical restraint (i.e., used for convenience or discipline). There are studies that suggest these drugs were used off-label for indications that were shown to be evidence-based. A systematic review of off-label use of second-generation antipsychotics by the Agency for Healthcare Research

<sup>4-1</sup> Briesacher, B. A., Limcangco, R., Simoni-Wastila, L., Doshi, J.A., Levens, S.R., Shea, D. G. & Stuart, D. (2005). The quality of antipsychotic drug prescribing in nursing homes. *Archives of Internal Medicine*, 164, 1280-1285.

<sup>4-2</sup> 42 CFR § 483.25(l) (1).

<sup>4-3</sup> Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices. Rockville, Md, US Food and Drug Administration, 2009. Available at [www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm](http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm).

<sup>4-4</sup> Kamble, P., Chen, H., Sherer, J., & Aparasu, R. R. (2008). Antipsychotic Drug Use Among Elderly Nursing Home Residents in the United States. *The American Journal of Geriatric Pharmacotherapy*, 6(4).

and Quality (AHRQ) reports that there is evidence that supports off-label use.<sup>4-5</sup> AHRQ's review found moderate strength of evidence for the efficacy of certain second-generation antipsychotics (namely olanzapine, risperidone, and quetiapine) in the treatment of behavioral problems in dementia. Another study examined off-label and evidence-based use of second-generation antipsychotic agents among nursing home residents and found that 57 percent of the second-generation antipsychotics prescribed were for FDA-approved indications or indication for which AHRQ found moderate strength of evidence during the study period.<sup>4-6</sup> Nevertheless, the finding that the remaining over 40 percent of second-generation antipsychotic drug use was without strong scientific support suggests sub-optimal quality of care in nursing homes.<sup>4-7</sup>

## **Prevalence**

A 2011 report from the Office of Inspector General (OIG) on atypical antipsychotic drugs indicated that 14 percent of elderly nursing home residents had at least one Medicare claim for an atypical antipsychotic drug. The OIG's findings indicated that 22 percent of these drugs were not administered according to CMS standards for drug therapy.<sup>4-8</sup>

Analysis of the 2004 National Nursing Home Survey (NNHS) showed that the prevalence rate of antipsychotic drug use among elderly nursing home residents was nearly 25 percent.<sup>4-8</sup> The most frequently reported diagnoses among antipsychotic users were dementia (70 percent), depression (41 percent), and anxiety (18 percent), which are off-label conditions.

In California, the prevalence rate of antipsychotic use in the absence of psychotic or related conditions has been above the national average, but has shown a slight decrease from 47.4 percent in Quarter 4, 2007 to 44.6 percent in Quarter 3, 2010, as shown in Figure 1.<sup>4-9</sup>

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<sup>4-5</sup> Shekelle, P., Maglione, M., Bagley, S. et. al. (2007). Comparative Effectiveness of Off-Label Use of Atypical Antipsychotics: Comparative Effectiveness Review No. 6. Rockville, MD. Agency for Healthcare Research and Quality.

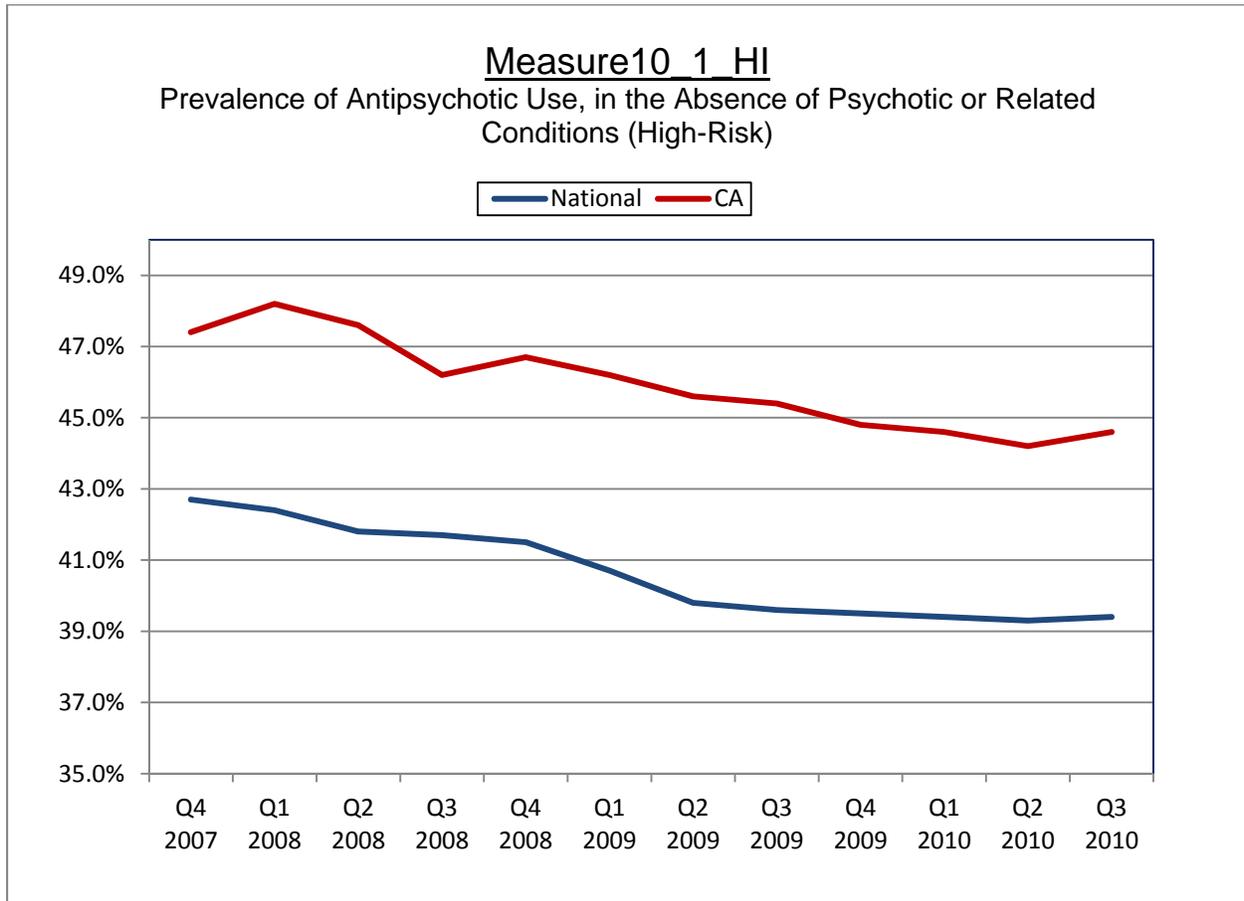
<sup>4-6</sup> Kamble, P., Sherer, J., Chen, H. & Aparasu, R. (2010). Off-Label Use of Second-Generation Antipsychotic Agents Among Elderly Nursing Home Residents. *Psychiatry Services*, 6(2).

<sup>4-7</sup> Ibid.

<sup>4-8</sup> Levinson, D. R. (2011). Medicare atypical antipsychotic drug claims for elderly nursing home residents. Office of Inspector General. Department of Health and Human Services. <http://oig.hhs.gov>

<sup>4-9</sup> CMS. MDS Quality Measure/Indicator Report. <https://www.cms.gov/MDSPubQIandResRep>.

**Figure 1—Comparison of California and National Antipsychotic Prevalence Rates using MDS 2.0 data Q4 2007 to Q3 2010**



There is evidence of high use of antipsychotic drugs in nursing homes. Although these drugs may be appropriate for off-label use, the fact that the California rate is higher than national average indicates that there are opportunities for improvement. Therefore, this may be an important measure to evaluate and incorporate into the QAP.

### Existing Performance Measure

An antipsychotic use measure, Prevalence of Psychoactive Medication Use in Absence of Psychotic or Related Condition, is currently being collected as part of the CASPER QM derived from MDS 3.0 and could potentially be incorporated into the QAP. This measure was available prior to November 2010 using MDS 2.0 data elements, and has been adapted for continued use based on MDS 3.0 data. It is calculated in the same manner as the previous MDS 2.0 QI/QM.

This measure reports the prevalence rate of antipsychotic use in all long stay residents with a target assessment who are receiving antipsychotics on one or more days during the last seven days, except those with psychotic or related conditions. The following exclusions apply: admission assessment, one or more psychotic disorders such as schizophrenia, Tourette’s, Huntington’s, and

presence of hallucinations on target assessment.<sup>4-10</sup> Currently, CMS is refining the current MDS 3.0 CASPER QM antipsychotic drug use and may have additional measures on this topic for future implementation in the Nursing Home Quality Reporting Initiative. The MDS 3.0 measure specifications can be found in Appendix A.

### ***Potential Adoption into the QAP***

As documented throughout this section, inappropriate antipsychotic use is an important topic of care to evaluate because it is focused on evaluating medication quality of care issues. More specifically, it focuses on doses exceeding maximum levels, duplicative therapy, or inappropriate indications according to the guideline. In addition, the rate of antipsychotic drug use in the absence of psychotic or related conditions among California nursing homes is higher than the national average, which suggests that there is opportunity to improve on this measure among facilities in California.

Using the previously proposed measure selection criteria, HSAG conducted an evaluation of the MDS 3.0 Casper QM antipsychotic drug use indicator, with the understanding that CMS is working on refining this into one or more quality measures.

- ◆ **Importance:** There is evidence of high use of antipsychotic drugs in nursing homes with rates nearing 45 percent in Quarter 3 of 2010. Further, there is a demonstrable gap in performance among California nursing homes on this measure. The prevalence rate of antipsychotic use in the absence of psychotic or related conditions has been above the national average, as shown in Figure 1. Although these drugs may be appropriate for off-label use, the fact that the California rate is higher than national average indicates that there are opportunities for improvement.
- ◆ **Scientific Acceptability:** Although the actual validity and reliability testing of the measure was not found, the reliability measurements for MDS 3.0 data elements are available. The MDS 3.0 item reliabilities from the National Evaluation Study show high agreement in Section N Medication items ranging from 0.986-0.997.<sup>4-11</sup> CMS is refining this measure and will have more information on this criterion in by the end of the year.
- ◆ **Feasibility:** This measure is based on the MDS 3.0 and does not impose additional burden to providers.
- ◆ **Usability:** This measure is currently in use and is available to nursing home facilities as part of CASPER QM reporting. As such, nursing home providers are familiar with this measure. However, a more refined measure with increased reliability and validity may not be available until early next year, and having at least a year of public reporting of the measure would be beneficial to ensure the measure's usability.

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<sup>4-10</sup> QM/QI Reports Technical Specifications: Version 1.1 . A-17

<sup>4-11</sup> Saliba, D. & Buchanan, J. (2008). Development and Validation of a Revised Nursing Home Assessment Tool: MDS 3.0. Appendix A MDS 3.0 Reliabilities Summary Table. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIMDS30.html>

- ◆ **Comparison to Related or Competing Measures:** There are no related or competing measures. Adopting a measure that is aligned with the CMS national Partnership for Dementia Care would reduce confusion for consumers and providers alike.

## Summary

HSAG recommends that the State consider adopting a measure related to medication quality of care issues. Specifically, HSAG recommends using the CMS antipsychotic medication measure or measures after it has undergone further refinement and received NQF endorsement. There is indication of high use of antipsychotic drugs in nursing homes, as well as a demonstrable gap in performance among California nursing homes as illustrated by California's higher than national average rates. The measure will be based on MDS 3.0 and will not impose additional data collection burden to nursing home providers. Adopting this measure will align with the CMS national initiative: The Partnership for Dementia Care, and will reduce confusion for consumers and providers alike. While the current QM/QI measure is available from the Casper database, HSAG recommends using the measure that will be further refined by CMS to ensure the measure's reliability and validity.

## 5. CONCLUSIONS

AB 19 requires the State to consider incorporating additional performance measures, including the use of chemical restraints, into the QAP. After conducting an extensive environmental scan, HSAG was unable to find a quality measure focused on chemical restraints that the State can use for the QAP.

The concept of chemical restraints is complex, and difficult to define and operationalize for measurement. A major barrier to developing a measure for chemical restraints is the unavailability of an electronic data source that combines information on drugs given to a resident and reasons for giving that drug. This would require a data collection strategy that involves the use of drug claims data (such as Part D) and medical record review. A second barrier is the difficulty in establishing the fact that the medications were prescribed for convenience or discipline, since this is not usually evident or documented in the medical records. There are no existing quality measures for chemical restraints that the State can use for the QAP. Moreover, it is not possible to develop a quality measure on chemical restraints. These methodological issues compromise the validity and reliability of a chemical restraint measure. At this time, HSAG does not believe it is feasible to implement a chemical restraint use measure in the QAP. If more suitable data sources are available in the future, HSAG recommends that the State re-evaluate the feasibility of developing such a measure.

Given that chemical restraint use cannot be implemented at this time, adopting a quality measure related to medication quality of care issues is an option. It is important to note that inappropriate use of antipsychotic drugs should not be considered a substitute for measuring chemical restraints. However, there is indication of high use of antipsychotic drugs in nursing homes, as well as a demonstrable gap in performance among California nursing homes as illustrated by California's higher than national average rates. HSAG recommends that the State consider using the CMS antipsychotic medication measure. CMS is further refining the Casper QM antipsychotic drug use indicator, and developing it into quality measures. The quality measures will be based on MDS 3.0 and will not pose additional data collection burden to nursing home providers. Further, if these measures are adopted into the program, the State will be in alignment with CMS's initiative on ensuring appropriate antipsychotic drug use in nursing home residents.

## 6. APPENDIX A. MDS 3.0 MEASURE SPECIFICATIONS

The CASPER QM psychoactive medication prevalence measure derived from MDS 3.0. The MDS 3.0 measure specifications are below:

- ◆ **Measure Name:** Prevalence of Psychoactive Medication Use in Absence of Psychotic or Related Condition.
- ◆ **Numerator:** Long-stay residents with a selected target assessment where the following condition is true: antipsychotic medications received. This condition is defined as follows:
  - For assessments with target dates on or before 03/31/2012: N0400A = [1].
  - For assessments with target dates on or after 04/01/2012: N0410A= [1,2,3,4,5,6,7].
- ◆ **Denominator:** All long-stay residents with a selected target assessment, except those with exclusions.
- ◆ **Exclusions:**
  - The resident did not qualify for the numerator and any of the following is true:
    - For assessments with target dates on or before 03/31/2012: N0400A = [-].
    - For assessments with target dates on or after 04/01/2012: N0410A=[-].
  - Any of the following related conditions are present on the target assessment (unless otherwise indicated):
    - Schizophrenia (I6000 = [1]).
    - Psychotic disorder (I5950 = [1]).
    - Manic depression (bipolar disease) (I5900 = [1]).
    - Tourette's Syndrome (I5350 = [1]).
    - Tourette's Syndrome (I5350 = [1]) on the prior assessment if this item is not active on the target assessment and if a prior assessment is available.
    - Huntington's Disease (I5250 = [1]).
    - Hallucinations (E0100A = [1]).
    - Delusions (E0100B = [1]).