On October 4, 2016 CMS released the final revised requirements for participation, aka, the Mega Rule. This is a summary of relevant points from ASCP’s comments in comparison to the Final Rule. Implementation phases:

- Phase 1: November 28, 2016
- Phase 2: November 28, 2017
- Phase 3: November 28, 2019

§483.5 Definitions: CMS has added some definitions in the final rule. Implementation phase 1.

ASCP recommended that Pharmacists be added to the definition of Licensed Health Professional (§483.5). Additionally, ASCP recommends a phased in implementation of the provisions in this proposed rule to improve electronic systems consistent with the Office of the National Coordinator for Health Information Technology (ONC) interoperability roadmap.

Final Rule: A licensed health professional is a physician; physician assistant; nurse practitioner; physical, speech, or occupational therapist; physical or occupational therapy assistant; registered professional nurse; licensed practical nurse; or licensed or certified social worker; or registered respiratory therapist or certified respiratory therapy technician.

Note: The definition does not include pharmacists. CMS explains that the term is defined in statute at section 1819(b)(5)(G) of the Social Security Act and the agency doesn’t have authority to re-define the term.
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<tr>
<th>§483.21 Comprehensive Person-Centered Care Planning - New Section</th>
<th>ASCP recommended 72 hours for care plan. Include consultant and dispensing pharmacist. And pharmacist notification upon admission. ASCP recommended the consultant pharmacist is included in care plan development. A CP completes a CMR during key transitions of care.</th>
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Final Rule:
• Facilities must develop and implement a baseline care plan for each resident, within 48 hours of their admission, which includes the instructions needed to provide effective and person-centered care that meets professional standards of quality care.

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<th>§ 483.21(c) (2) (iii), (iv) Medication Reconciliation upon discharge: Implementation Phase 1 with the following exceptions:</th>
<th>ASCP recommended interoperability, including inter-professional collaboration, pharmacists being able to order and include pharmacists recommendations as part of the medical record</th>
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<td>• Baseline care plan—Implemented in Phase 2.</td>
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Final Rule: Physicians have to report on pharmacist recommendations, including rationale for their decision to either follow, or reject the pharmacist recommendations. Medication reconciliation is required to be a part of the discharge summary.

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<th>§ 483.45. Pharmacy Services: DRR. Implementation Phase 1</th>
<th>ASCP supported CMS’ proposed provisions for pharmacy services. While the expectation is that consultant pharmacists’ monthly review includes a review of the medical record, ASCP believes it is appropriate that in addition to current monthly MRRs, CMS require additional reviews of the medical record when specific circumstances dictate. ASCP also believes that the consultant pharmacist must have full access to the complete medical record in order to properly complete these reviews.</th>
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Final Rule: requires a pharmacist to perform a drug regimen review (DRR) for each resident at least once a month. In addition to the attending physician and director of nursing, who already receive the DRR, CMS is requiring the facility’s medical director to get a copy of the
DRR. Finally, facilities are required to develop policies and procedures concerning the DRR including timeframes, pharmacist procedures, and notification procedures.

| § 483.45(d) Unnecessary Drugs: Implementation Phase 1 | ASCP supported F329 that defined unnecessary medication as “in excessive dose (including duplicative therapy); or, for excessive duration, without adequate monitoring; or, without adequate indications for use; or, in the presence of adverse consequences which indicate the dose should be reduced or discontinued.” We supported expanding this to include medications given without medical necessity. |

Final Rule: Unnecessary Drugs-A resident’s drug regimen must be free of unnecessary drugs. An unnecessary drug is any drug when used in:

- Excessive dose (including a duplicate drug)
- Excessive duration
- Without adequate monitoring
- Without adequate indication for its use
- In the presence of adverse consequences which indicate the dose should be reduced or discontinued, or
- Any combination of the above.

483.45(e) Psychotropic Drugs: Implementation Phase 2 (date) | ASCP Expressed concern that the definition was too broad and could impede administration of opioid anagesic medications and any medication that could cause dizziness, sleepiness, or changes in behavior. Further, we highlighted clinical issues with broad GRD requirements. GDR should apply only when it is in the best interest of the patient. ASCP suggested CMS consider a longer period of time for PRN, such as 7 days, so that medications are not stopped too soon. |

Final Rule: Psychotropic drugs-
- We are revising existing requirements regarding “antipsychotic” drugs to refer to “psychotropic” drugs and define “psychotropic drug” as any drug that affects brain activities associated with mental processes and behavior. We are requiring several provisions intended to reduce or eliminate the need for psychotropic drugs, if not
clinically contraindicated, to safeguard the resident’s health. Opioid analgesics are excluded from the definition. Based on a comprehensive assessment of a resident, the facility must ensure that

- 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;
- Residents who receive these drugs must receive gradual dose reductions and behavioral interventions, unless otherwise contraindicated, in an effort to discontinue these drugs;
- Residents are not to receive PRN orders for psychotropic drugs unless the drug is intended to treat a condition that is documented in the clinical record;
- PRN orders are limited to 14 days, unless the prescriber believes it is appropriate to extend the order beyond 14 days and documents this in the clinical record;
- PRN orders cannot be renewed beyond 14 days unless the prescriber has evaluated the resident for the appropriateness of the medication.
- If the prescriber believes the resident requires an antipsychotic drug on a PRN basis for longer than 14 days, he/she will be required to write a new PRN script every 14 days after the resident has been evaluated. (details in subregulatory guidance)

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<th>483.80: Infection Control: Implementation Phase 1 with the following exceptions:</th>
<th>ASCP Recommended that CMS must give clearer guidance on the expected qualifications of the IPCO in order to make this position a beneficial addition to the clinical staff at a skilled nursing facility. Additionally, ASCP recommends that CMS recognize the consultant pharmacist as an ideal candidate for this position.</th>
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<td>• As linked to Facility Assessment at §483.70(e)—Implemented in Phase 2.</td>
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<td>• (a)(3) Antibiotic stewardship—Implemented in Phase 2.</td>
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<tr>
<td>• (b) Infection prevention (IP)—Implemented in Phase 3.</td>
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<td>• (c) IP participation on QAA committee—Implemented in Phase 3.</td>
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CMS is requiring facilities to develop an Infection Prevention and Control Program (IPCP) that includes an Antibiotic Stewardship Program and designate at least one Infection Preventionist (IP).

Additional Highlights:

- Expanded required elements of facility Infection Prevention & Control Program (IPCP).
- Annual review of facility IPCP and update program as necessary.
- Specific qualification requirements for Infection Preventionist.
- Infection Preventionist must be member of QAA committee and report on IPCP on a regular basis.
- Incorporates language change from resident’s legal representative to resident’s representative.