I. Medicare Inpatient Prospective Payment System Final Rule for FFY 2014

A. Overview.

On August 19, 2013, the Centers for Medicare and Medicaid Services (CMS) published the Medicare Program: Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Payment Policies Related to Patient Status for FY 2014 final rule (Final Rule) 78 F.R. 50496, August 19, 2013. CMS states that the Final Rule revises the Medicare Hospital Inpatient Prospective Payment Systems (IPPS) for operating and capital related costs of acute care hospitals to implement changes arising from CMS’s continuing experience with these payment systems. Id. CMS states that these changes will be applicable to Medicare discharges occurring on or after October 1, 2013, unless otherwise stated in the Final Rule. Id.

CMS also updates the payment policies and annual payment rates for the Medicare prospective payment systems (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) and is implementing certain statutory changes that were applied to the LTCH PPS by the Affordable Care Act. Id. Again, these updates and statutory changes would be applicable to discharges occurring on or after October 1, 2013, unless otherwise specified in the Final Rule. Id.

CMS also made a number of changes relating to direct graduate medical education (GME) and indirect medical education (IME) payments. Id. CMS established new requirements or revised requirements for quality

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1 Jeffrey S. Moore would like to thank Eugenia Stark Thomas, Larry McCarty, S. Blake Adams and Sara E. Budslick of Phelps Dunbar for their contribution to this outline.
reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities that are participating in Medicare). *Id.*

CMS updated policies relating to the hospital value-based purchasing (VBP) program and the hospital readmissions reduction program. *Id.* CMS also revised the conditions of participation (CoPs) for hospitals relating to the administration of vaccines by nursing staff as well as the CoPs for critical access hospitals relating to the provision of acute inpatient services. *Id.* Finally, CMS finalized proposals issued in two (2) separate proposed rules addressing payment policies related to patient status: payment of Medicare Part B inpatient services; and admission and medical review criteria for payment of hospital inpatient services under Medicare Part A. *Id.*

**B. Fiscal Year 2014 Payment Update**

The Final Rule increases overall hospital payments (capital and operating) by $1.2 billion. *Id.* at 51037. The Final Rule would increase IPPS operating rates by .7% after accounting for inflation and other adjustments required by law. *Id.* at 50607-50608. This increase represents a temporary reduction of .8% to the Federal operating rate in FY 2014 that was authorized by Congress as part of the American Taxpayer Relief Act to recoup overpayments from prior years as a result of a new patient classification system that better recognizes patient severity of illness. *Id.* CMS is also making an additional .2% reduction to offset projected spending increases associated with changes to admission and medical review criteria for inpatient hospital services. *Id.* at 50506, 50508, and 50746. CMS has projected that its new inpatient admission guidance will increase inpatient payments by approximately $220 million. *Id.* In order to maintain IPPS budget neutrality, CMS is applying a .2% reduction to the Federal operating, hospital-specific and Federal capital rates. *Id.*

CMS projects that LTCH PPS payments will increase by 1.3%, or approximately $72 million in FY 2014. *Id.* at 50508.

**C. Revised Admission and Medical Review Criteria for Inpatient Services (78 F.R. at 50,906-50,954)**

1. **Two-Midnight Benchmark and Presumption**

   In the Final Rule, CMS revised its guidance on determining when hospital inpatient admissions are reasonable and necessary and, therefore, correctly paid under Medicare Part A. More specifically, CMS finalized two (2) distinct yet related rules: the “two-midnight benchmark” and “two-midnight presumption.” *Id.* at 50,952. Previously, physicians were to use a twenty-four (24)
hour benchmark when determining patient status as an inpatient or outpatient. In other words, physicians were to admit beneficiaries whom they expected would need hospital care for at least twenty-four (24) hours and treat other beneficiaries in the outpatient setting. Now, physicians must use a two-midnight benchmark to determine whether a patient should be admitted as an inpatient:

We are specifying that for those hospital stays in which the physician expects the beneficiary to require care that crosses two midnights and admits the beneficiary based upon that expectation, Medicare Part A payment is generally appropriate. Conversely, we are specifying that hospital stays in which the physician expects the patient to require less than two midnights, payment under Medicare Part A is generally inappropriate. Id. at 50,506.

The regulations continue to focus on the physician’s “reasonable and supportable expectation, not the actual length of care,” when determining patient status. Id. at 50,945.

The Final Rule also implements a “two-midnight presumption” which directs contractors to presume a reasonable and necessary inpatient admission for hospital stays crossing two midnights. Id. at 50,952. CMS instructs contractors to disregard that presumption, however, if they find “evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the two-midnight presumption.” Id. at 50,925.

Significantly, CMS predicts a net increase in inpatient encounters because of the new two-midnight benchmark and, therefore, less beneficiary liability. Id. at 50,746. These estimated shifts, according to CMS and its actuaries, project a net increase of 40,000 inpatient encounters in 2014—an increase of approximately $220 million in IPPS expenditures. Id. Many commenters generally disagreed with this assessment, however, and especially disagreed with CMS’s adjustment of the IPPS payment rates (minus 0.2%) that was a result of this assessment. Id. at 50,953.

2. Physician Certification Requirements

As a condition of payment for hospital inpatient services under Medicare Part A, a physician must certify the medical necessity of providing such services on an inpatient basis. Physician
certification—which includes the inpatient admission order as a required element—plays a crucial role in demonstrating (along with other documentation in the medical record) that hospital inpatient services were medically necessary.


In the Sept. 5 Guidance, CMS states that physician certification for hospital inpatient services (other than inpatient psychiatric facilities) must include the following information:

- **Authentication of the practitioner order.** The physician must certify that the inpatient services were ordered in accordance with Medicare regulations. This includes a certification that the hospital inpatient services were reasonable and necessary, and in the case of services not specified as “inpatient only” under 42 C.F.R. § 419.22(n), that they are appropriately provided as inpatient services in accordance with the two-midnight rule.

- **Reason for inpatient services.** The certification must include the reasons for either (i) hospitalization of the beneficiary for inpatient medical treatment or a medically-required inpatient diagnostic study; or (ii) special or unusual services for cost outlier cases under the IPPS;

- **The estimated time the beneficiary requires or required in the hospital;**

- **The plans for post-hospital care, if appropriate; and**

- **(For Critical Access Hospitals (CAHs) only):** Certification that the beneficiary may reasonably be expected to be discharged or transferred to a hospital within ninety-six (96) hours after admission to the CAH.

Sept. 5 Guidance.

The certification must be completed, signed, and documented in the medical record prior to discharge, with the exception of (1) outlier cases, which must be certified and re-certified as provided in 42 C.F.R. § 424.13, and (2) CAH inpatient services, which must
be certified no later than one day prior to the date on which the
claim for payment for the inpatient CAH services is submitted in
accordance with 42 C.F.R. § 424.15. Sept. 5 Guidance.

Only the following types of practitioner, however, may sign the
certification: (1) a physician; (2) a dentist in the circumstances
specified in 42 C.F.R. § 424.13(d); or (3) a doctor of podiatric
medicine if his or her certification is consistent with the functions
he or she is authorized to perform under state law. Sept. 5
Guidance.

3. Inpatient Admission Order Requirements.

The second half of the Sept. 5 Guidance addresses requirements
for inpatient admission orders, which constitute a required element
of physician certification. A Medicare beneficiary is considered an
inpatient of a hospital only if the beneficiary is formally admitted
as an inpatient pursuant to a valid order by a physician or other
qualified practitioner. Sept. 5 Guidance. The order must be
furnished at or before the time of the inpatient admission, as CMS
does not permit retroactive orders. Sept. 5 Guidance. Additionally,
the order must be authenticated prior to discharge and such
authentication may be performed and documented as part of
the physician certification discussed above. Sept. 5 Guidance.

D. Hospital-Acquired Condition (HAC) Reduction Program (78 F.R. at
50707-50729)

As part of the new HAC reduction program created by the Affordable
Care Act, beginning in FY 2015 hospitals with a significant number of
HACs will be penalized with respect to their IPPS reimbursement. Id. at
50708. Specifically, hospitals with a HAC score that falls within the top
25% of total HAC scores for all eligible hospitals will be subject to a 1.0%
reduction in their IPPS payments. Id.

E. Hospital Readmissions Reduction Program (78 F.R. at 50649-50664)

In October 2012, Medicare began encouraging hospitals with excess
30-day readmissions to lower 30-day readmission rates for the conditions
of heart attack, heart failure and pneumonia by reducing a portion of the
hospital’s payments by up to 1%, depending on the hospital’s performance
on key readmissions measures. Id. at 50649. As required by law, the
Final Rule increases the maximum reduction of payments to up to 2%. Id.
at 50668. For FY 2015, CMS is adopting its proposal to add three
readmission measures for evaluation under the readmissions reduction
program. In addition to the current acute myocardial infarction, heart
failure and pneumonia measures, CMS will evaluate readmissions for
patients admitted for an acute exacerbation of chronic obstructive pulmonary disease and patients admitted for elective total hip arthroplasty and total knee arthroplasty. *Id.* at 50663. In addition, CMS has increased the number and types of planned readmissions that no longer count against a hospital’s readmission rate.

F. Medicare Disproportionate Share Hospitals (78 F.R. at 50613-50647)

The ACA requires CMS to implement significant changes to the current Medicare DSH payment policies. These changes will reduce and redistribute DSH payments to hospitals nationwide beginning October 1, 2013 for FY 2014.

Effective for discharges on or after October 1, 2013, DSH hospitals will receive 25% of the DSH payments that they would have received under the previous traditional DSH payment methodology, an amount that CMS refers to as the “empirically justified Medicare DSH payment.” *Id.* at 50620-50621. The remaining amount of DSH funding (equal to approximately 75% of what would have been paid under the previous methodology) will first be reduced to reflect changes in the percent of individuals younger than 65 who are uninsured, and then will be distributed to hospitals that qualify for DSH that have provided uncompensated care. *Id.* at 50621. This payment is referred to by CMS as the “uncompensated care payment.” *Id.* The uncompensated care payment will be based on the hospital’s amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that received DSH payments for that fiscal year. *Id.*

Significantly, the Affordable Care Act provides that there shall be “no administrative or judicial review under Section 1869, Section 1878, or otherwise” of “any estimate of the Secretary for purposes of determining the factors described in paragraph (2),” or of “any period selected by the Secretary” for the purpose of determining those facts. *Id.* Therefore, according to CMS, there can be no administrative or judicial review of the estimates developed for purposes of applying the three factors used to determine uncompensated care payments, or the periods selected in order to develop such estimates. *Id.*

G. Expiration of Moratorium on 25% Patient Threshold Payment Adjustment Policy for LTCHs (78 F.R. at 50768-50772).

CMS did not extend the moratorium on the application of the “25% threshold” payment adjustment for LTCHs, which provides that certain LTCHs will be subject to a Medicare payment reduction if more than 25% of their patients are admitted from a particular referring hospital. *Id.* at 50508. Therefore, the payment adjustment for LTCHs that admit more
than 25% of their patients from a particular hospital will go into effect for discharges on or after October 1, 2013. *Id.*

**H. Payment of Part B Hospital Inpatient Services (78 F.R. at 50908-50938)**

In general, CMS requires that claims for stays of less than two midnights be billed under Medicare Part B as an outpatient service beginning October 1, 2013. *Id.* at 50924. CMS finalized a policy in the Final Rule permitting hospitals to rebill an expanded list of services under Medicare Part B after a Part A claim is denied for lack of medical necessity, or is not paid based on a self-audit by submitting a no pay-provider liable Part A claim before submitting Part B claims. *Id.* at 50908-50914. CMS states that it will pay for therapy services as Part B inpatient therapy services furnished to hospital inpatients whose admissions are determined to be not reasonable and necessary under Medicare Part A. *Id.* at 50910. CMS states that it is finalizing its proposal to exclude observation services, outpatient DSMT and hospital outpatient visits from Part B inpatient payment. *Id.* at 50912. CMS reasons that these services should only be furnished to hospital outpatients, and, therefore, it does not believe hospitals will need to bill these services on Part B inpatient claims. *Id.*

With respect to the time limit for rebilling Part B inpatient claims, CMS finalized its proposal to require that Part B inpatient claims be rebilled to Medicare within one (1) calendar year from the date of service provided. *Id.* at 50922-50924. However, CMS is modifying what it stated in the proposed rule regarding the applicability of the CMS-1455-R ruling. *Id.* Specifically, hospitals are permitted to follow the Part B billing time frames established in the CMS-1455-R ruling regarding appeals and the submission of Part B claims after the effective date of the Final Rule, provided (1) the Part A inpatient claim denial was one to which the ruling originally applied; or (2) the Part A inpatient claim has a date of admission before October 1, 2013 (the effective date of this Final Rule), and is denied after September 30, 2013, on the grounds that the medical care was reasonable and necessary, but the inpatient admission was not. *Id.* at 50924.

**II. Medicare Outpatient Prospective Payment System Final Rule for CY 2014**

**A. Overview.**

On December 10, 2013, the Centers for Medicare and Medicaid Services (“CMS”) published the *Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement...*
Determination and Appeals; Final Rule for Calendar Year 2014.
78 F.R. at 74826 (Dec. 10, 2013). (“OPPS Final Rule”). The OPPS Final Rule is the annual update to Medicare payment policies and rates for hospital outpatient departments and ASC services. Under the Final Rule, total CY 2014 OPPS payments are expected to increase by $4.4 billion (a 9.5% increase) and CY 2014 Medicare payments to ASCs are expected to increase by approximately $143 million (a 5.3% increase) over CY 2013. The full text of the final rule may be found at 78 F.R. 74826 (Dec. 10, 2013), or online at http://www.gpo.gov/fdsys/pkg/FR-2013-12-10/pdf/2013-28737.pdf.

B. Key Changes to the OPPS Payments and Policies

1. OPPS Payment Rate – The OPPS Final Rule increases the overall OPPS market basket rate by 1.7%. This represents a 2.5% market basket increase for inpatient services paid under the Inpatient Prospective Payment System (“IPPS”) less a multifactor productivity adjustment of .5% and a .3% adjustment required by the Affordable Care Act. (78 F.R. at 74949-74950.)

2. Coding for Outpatient Clinic and Emergency Department Visits – The final rule replaces the current five levels of outpatient clinic visit codes with a single Healthcare Common Procedure Coding Systems (“HCPCS”) code and associated Ambulatory Payment Classification (“APC”) category describing all clinic visits. This simplification sets a single payment rate based upon the total mean costs for the associated service levels being adopted for consolidation. The new single level of payment for clinic visits will apply to both new and established patients. (78 F.R. at 75036-75043.)

3. Expanded Categories of “Packaged” Items or Services – For CY 2014, CMS has finalized five new categories of supporting items and services which will be “packaged” into a single payment for the primary diagnostic or therapeutic service under the OPPS. The categories include:

   a. Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure;

   b. Drugs and biologicals that function as supplies when used in a surgical procedure;

   c. Certain clinical diagnostic laboratory tests;

   d. Certain procedures described by add-on codes; and

   e. Certain device removal procedures.
CMS also finalized a proposal to package payment for 150 items and services currently paid separately under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) fee schedule. (78 F.R. at 74925-74948.)

4. Comprehensive APCs for Device-Dependent Procedures – The CY 2014 final rule establishes 29 comprehensive APCs to replace the 29 existing device-dependent APCs for the most costly device-dependent procedures. However, CMS is delaying implementation of the new APCs until CY 2015. The comprehensive APCs will bundle payment for all individually-reportable codes that represent the provision of the primary service and all adjunctive services that are integral to or support the delivery of the primary service. This includes diagnostic procedures, lab tests, and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure, coded and uncoded services and supplies used during the service; outpatient department services delivered by therapists as part of the comprehensive service, and durable medical equipment as well as supplies to support that equipment, and any other components reported by HCPCS codes that are provided during the comprehensive service. (78 F.R. at 74861-74910.)

5. Data Collection for Provider-Based Outpatient Clinics – CMS announced in the CY 2014 OPPS/ASC and MPFS proposed rules that it was considering collecting data to better understand the growing trend toward hospital acquisition of physician offices and subsequent treatment of those locations as off-campus provider-based outpatient departments. CMS expressed interest in collecting information that would allow it to analyze the frequency, type, and payment of services furnished in off-campus provider-based hospital departments. In the CY 2014 OPPS final rule, CMS responded to several industry comments on this topic and announced that it would take the public comments received into consideration as it continued to consider approaches to collecting data on services furnished in off-campus provider-based departments. (78 F.R. at 75061-75062.)

6. Physician Supervision Policies – CMS adopted a proposal to begin applying a direct supervision requirement for outpatient therapeutic services in Critical Access Hospitals (CAHs) and small rural hospitals in CY 2014. CMS had previously exempted such hospitals from this requirement. Beginning January 1, 2014, all outpatient therapeutic services furnished in hospitals and CAHs will require a minimum of direct supervision, unless the service is on a list of services that may be furnished under general supervision or is designated as a nonsurgical extended duration
therapeutic service. The CMS website maintains a list of these exempt services at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CY2013-OPPS-General-Supervision.pdf. (78 F.R. at 75056-75057.)

CMS also finalized a proposed clarification regarding physician supervision requirements for observation care. The final rule clarifies that once a supervising physician or appropriate non-physician practitioner determines and documents in the medical record that a beneficiary is stable and may be transitioned to general supervision, general supervision may be furnished for the duration of the observation services. CMS does not require an additional initiation period(s) of direct supervision during the service. (78 F.R. at 75057.)

Finally, CMS finalized a proposal making it an express condition of Medicare Part B payment that hospital or CAH outpatient “incident to” services must be personally provided by an individual who is qualified to furnish such services under the scope of practice laws of the State in which the services are provided. (78 F.R. at 75058-75061.)


A. Overview

On December 27, 2013, CMS issued a proposed rule to establish emergency preparedness requirements for certain healthcare providers and suppliers participating in the Medicare and Medicaid programs to increase patient safety during emergencies and to establish a more coordinated response to natural and man-made disasters. (78 F.R. 79082, December 27, 2013.)

According to CMS, the proposed rule would establish as conditions of participation or conditions of coverage national emergency preparedness requirements for certain Medicare and Medicaid participating providers and suppliers to insure that they adequately plan for both natural and man-made disasters, and coordinate with Federal, state, tribal, regional, and local emergency preparedness systems. Id. The rule would also ensure that these providers and suppliers are adequately prepared to meet the needs of patients, residents, clients and participants during disasters and emergency situations. Id.

B. Background

CMS states in the proposed rule that over the past several years, the United States has been challenged by several natural and man-made
disasters, including, but not limited to, the September 11, 2001 terrorist attacks, the subsequent Anthrax attacks, catastrophic hurricanes in the Gulf Coast states in 2005, flooding in the Midwestern states in 2008, tornados and floods in the spring of 2011, the 2009 H1N1 influenza pandemic and Hurricane Sandy in 2012. Id. at 79084. As a result of these emergency situations, readiness for public health emergencies has been put on the national agenda. Id. The proposed rule defines an “emergency” or “disaster” as an event affecting the overall target population or the community at large that precipitates the declaration of a state of emergency at a local, state, regional or national level by an authorized public official such as governor, the Secretary of HHS or the President of the United States. Id.

The organizations affected by this proposed rule include hospitals (including CAHs), long-term care facilities, ambulatory surgical centers, hospices, home health agencies, outpatient rehabilitation providers, programs of all-inclusive care for the elderly, organ procurement organizations, religions non-medical healthcare institutions, community mental health centers, rural health clinics and end-stage renal disease facilities. Id. at 79091-79176.

Along with other requirements, the proposed rule would require facilities that participate in Medicare or Medicaid to address four core components of emergency preparedness:

1. Emergency Plan – Based on a risk assessment, develop an emergency plan using an all-hazards approach focusing on capacities and capabilities. Id. at 79092-79095.

2. Policies and Procedures – Develop and implement policies and procedures based on the plan and risk assessment. Id. at 79095-79099.

3. Communication Plan – Develop and maintain a communication plan that complies with both federal and state law. Patient care must be well coordinated with the facility, across healthcare providers, and with state and local public health departments and emergency systems. Id. at 79099-79100.

4. Training and Testing Program – Develop and maintain training and testing programs, including initial and annual trainings, conducting drills and exercises or participating in an actual incident that tests the plan. Id. at 79100-79102.

The emergency preparedness proposed requirements are adjusted to reflect the characteristics of each type of provider and supplier. For example:
• Outpatient providers and suppliers will not be required to have policies and procedures for provision of subsistence needs. *Id.* at 79102-79103.

• Each organ procurement organization (OPO) must have an agreement with another OPO to provide procurement services in the event that the OPO cannot provide such services due to an emergency. *Id.* at 79103.

• Hospitals, critical access hospitals and long-term care facilities will be required to implement emergency and standby power systems based on their emergency plan. *Id.* at 79102.

Comments to CMS on the proposed rule were originally required to be filed by no later than February 25, 2014. However, on February 12, 2014, CMS published a notice in the Federal Register advising that the comment period would be extended to March 31, 2014 to give industry organizations more time to canvas their membership for input on the proposed rule. (Medicare and Medicaid Program: Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers; Extension of Comment Period, CMS-3178-N, February 12, 2014.)

IV. Modifications to HIPAA Privacy Rule and CLIA Program to Enhance Patients’ Access to Laboratory Test Reports

A. Overview

On February 6, 2014, the Centers for Medicare and Medicaid Services (CMS) published a final rule entitled, “CLIA Program and HIPAA Privacy Rule; Patients’ Access to Test Reports.” 79 F.R. 7290 February 6, 2014. The February 6 final rule modifies the implementing regulations to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as well as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule to impose significant new patient access obligations on CLIA and CLIA-exempt laboratories.

With respect to the CLIA regulations, the final rule allows laboratories subject to CLIA, upon the request of a patient (or the patient’s personal representative) to provide access to completed test reports that, using the laboratory’s authentication process, can be identified as belonging to that patient. *Id.* The final rule also clarifies that laboratories subject to CLIA may provide a copy of the patient’s test reports to a person or entity designated by the patient to receive such reports in accordance with the HIPAA Privacy Rule at 45 C.F.R. § 164.524(c)(3)(ii). *Id.* at 7297-7298. The final rule retains the CLIA regulatory provision that requires the release of test reports only to authorized persons, to the persons
responsible for using the test reports, and to the laboratory that initially requested the test. *Id.* at 7290.

With respect to the HIPAA Privacy Rule, the February 6 final rule removes the exceptions to an individual’s right of access at § 164.524(a)(1)(iii) related to CLIA and CLIA-exempt laboratories. *Id.* at 7292. Thus, as of the compliance date of the final rule, HIPAA-covered laboratories will be required to provide an individual (or the individual’s personal representative) with access, upon request, to the individual’s completed test reports (and other information maintained in a designated record set) in accordance with the provisions of § 164.524 of the Privacy Rule. *Id.* CMS also noted that HIPAA-covered laboratories must revise their notices of privacy practices by the compliance date of the final rule to inform individuals of this right. *Id.* at 7303.

The CLIA modifications take effect on April 7, 2014. *Id.* at 7290. The compliance date for the modifications to the HIPAA privacy rule is October 6, 2014. *Id.*

V. Office of Medicare Hearings and Appeals - Medicare Appellant Forum (MAF)

A. Overview

On February 12, 2014, the Office of Medicare Hearings and Appeals (“OMHA”) held a MAF where OMHA provided “insight” into its plans for decreasing the ALJ backlog of Medicare appeals. A copy of OMHA’s PowerPoint presentation from the MAF can be accessed at [www.hhs.gov/omha/omha_medicare_appellant_forum_presentations.pdf](http://www.hhs.gov/omha/omha_medicare_appellant_forum_presentations.pdf). The forum focused on how OMHA will streamline the future appeals process and ways providers can help OMHA decrease the backlog and processing time for appeals.

The forum began with an overview of where the appeals process stands today. As providers already knew, the ALJs have received an increasing number of Medicare Part A appeals over the prior years—from 1,250 appeals per week in 2012 to 15,000 appeals per week as of January 2014. Currently, OMHA has 480,000 appeals awaiting assignment, and Chief Judge Nancy J. Griswold confirmed that all assignments of appeals have ceased. In fact, providers can expect a 10 to 20-week delay from the filing of an appeal (receipt at OMHA) until docketing. And after the appeal is docketed, providers can expect to wait more than 24 months before the appeal is assigned to an ALJ field office—and an additional 6+ months before scheduling of a hearing. Although Judge Griswold touted a 121% increase in ALJ productivity from 2009-2013, the appeals-to-decisions ratio currently stands at 4 to 1.
B. OMHA’S PROPOSED SHORT AND LONG-TERM SOLUTIONS

As Judge Griswold reiterated numerous times throughout the day, there is no single fix to this overwhelming burden of appeals at the ALJ level, and she emphasized that a “holistic approach” must be taken. To that end, she and other OMHA staff members introduced many ideas available for consideration, including:

- Opening a New Field Office: OHMA will be opening a new field office (either Central time zone or Mountain time zone) sometime this year.

- Staffing increases in existing field offices: appropriations increased 18.6% for FY 2014, which allows for additional staff and attorney support in existing offices.

- OMHA Adjudication Manual: The manual is expected to establish “most effective and uniform processes based on best practices” and address “day-to-day implementation of procedural rules.” OHMA intends to roll out sections of the manual intermittently in the coming months and will publish the manual on its website.

- Alternate Adjudication Models: OMHA plans to use pilot programs to determine the viability of additional tools and options for resolving claims.
  - Statistical Sampling: With provider consent, OMHA statisticians could extrapolate a sample of claims from a designated group and apply the error rate to the group of claims.
  - Alternative Dispute Resolution: An OMHA-facilitated mediation of claims.
  - Attorney Case Review: Use in-house attorneys to fast track potentially favorable claims or narrow issues for hearing.
  - Case Grouping: Although this already is an option available at a provider’s request (see discussion below), OMHA is considering grouping cases by provider and claim type.

- IT Solutions: OMHA is still a paper-based operation. Judge Griswold and her team plan to bring its document management systems into the 21st century with three initiatives:
  - ALJ Appeal Status Information System Website (AASIS): Expected to roll out May 2014, appellants will be able to check the status of their level 2 and level 3 appeals. This
website is anticipated to provide information on the appeal’s status, field office assignment, ALJ assignment, appeal status, and team phone number.

- Medicare Appeals Template System (MATS): a document generation system that uses fillable forms and population of data to create individualized decisions. This would help standardize decisions.

- Electronic Case and Adjudication Processing Environment (ECAPE): This system will replace OMHA’s existing case management system and make all aspects of case filing and adjudication electronic. Providers will be able to file their appeals online and check case status electronically while OMHA’s intake, case assignment, and scheduling functions will become automated. Exhibits, briefs, medical records, and other supplemental materials will be kept electronically and ALJs will be able to issue decisions and generate documents within this system. Rollout of this program will happen in stages, but it will not happen immediately. The request for proposal has yet to be issued, and once the contract is awarded, the program is expected to take 2 years before completion.

OMHA also noted other ways that providers can help streamline the process, including voluntary statistical sampling, grouping cases on their own accord, and waiving their right to a hearing if the provider has no additional information to submit. Although the previous examples might reduce the amount of time spent on each appeal, providers should consider these options warily and implement a strategy that will be most beneficial for winning the appeal in the most cost-effective way. As one commenter noted, statistical sampling will not be a viable option for providers if CMS continues to require that providers waive their right to rebill those claims. And as with the grouping of claims, providers should consider that only one ALJ will be involved with each statistical sample (ALJs have starkly differing overturn rates, ranging from 18% to 85%).

C. **DO’S AND DON’TS FOR FILING YOUR APPEALS AT ALL LEVELS**

OMHA supplied the audience with the strategic advice for providers to help streamline the appeals process. As providers now understand, OMHA will not accept briefs or additional evidence with the initial request for hearing. OMHA explained that providers should:

- Limit their requests to the Request for Hearing document, Appointment of Representative form, first page of the QIC
decision (for identification purposes), and proof of service to other parties.

- Not submit evidence already submitted to the lower levels of appeal, including prior appeals, medical records, and prior decisions (except for the first page of the QIC decision).

- Submit additional evidence and briefs directly to the ALJ once the case is assigned or within 10 days of the hearing notice.

During this session, Providers received inconsistent advice regarding the submission of appeals at the first, second, and third levels. For example, providers were asked to omit prior decisions from their third level appeals, but they were asked to include the demand letter and any prior decisions in their first and second level of appeals.

Although the forum provided a general overview of upcoming initiatives that OMHA will undertake to reduce the backlog of appeals, CMS had only a limited presence there and provided no hints at an interagency fix to the RACs’ increasing number of denials. OMHA said that it will issue a Federal Register notice soon with a request for comment on OMHA’s proposed methods to reduce the backlog. But as one commenter proclaimed, providers would be less worried with the delay if they were the ones “holding the dollars” rather than the RACs. One hundred and eleven (111) members of Congress recently issued a letter to Secretary Sebelius acknowledging that “[a]n alternative payment arrangement with auditors should be considered by the Congress and CMS in order to ensure RACS are not improperly incentivized to deny claims for profit and to ensure they focus on prevention of errors.”

VI. Case Law Developments

A. John Balko & Associates, Inc. v. Secretary of U.S. Department of Health and Human Services, No. 13-1568, (3rd Cir. February 12, 2014). On February 12, 2014, the United States Court of Appeals for the Third Circuit upheld a HHS ruling that a Medicare contractor could use statistical extrapolation to calculate Medicare overpayments paid to a nursing home care provider. Id. A Medicare contractor, Safeguard Services, audited John Balko & Associates, Inc.’s Balko’s reimbursement in 2008 after becoming concerned about reimbursement to the Medicare provider who was offering services to elderly patients in nursing homes. Safeguard’s audit determined that Balko had been paid for claims that were ineligible for Medicare payment. Based on a survey of 581 claims from 81 random beneficiaries, Safeguard identified a claims error rate of 99.85%. After adjusting for potential statistical error and applying the error rate to the universe of 5,445 claims, Safeguard calculated that Medicare had overpaid Balko $857,109.07. After several levels of
appeals, Balko had the error rate reduced to 77% with a revised extrapolated repayment amount of $641,437.00.

Balko appealed the reconsideration decision to the Administrative Law Judge arguing that Safeguard improperly used statistical extrapolation to calculate its overpayment. Under 42 U.S.C § 1395ddd(f)(3), Medicare contractors may use extrapolation to determine an overpayment amount in only two circumstances: if (1) there is a finding of “a sustained or high level of payment error,” or (2) there is evidence that the provider was informed of the payment error but failed to correct it. Balko argued that Safeguard’s use of extrapolation was inappropriate because Safeguard failed to find a high error rate (prior to conducting the audit).

On October 20, 2011, the ALJ ruled against Safeguard’s use of statistical sampling and extrapolation but sustained the overpayment findings on the specific claims audited. The ALJ held that there was no documentation to support a finding that either Balko had a high level of payment error or had been educated regarding any alleged payment errors prior to Safeguard’s extrapolation of an overpayment amount.

The Medicare Appeals Counsel (“MAC”) reviewed the ALJ’s ruling on its own motion and reversed the ALJ’s holding that Safeguard’s statistical sampling and extrapolation were invalid. The MAC vacated the ALJ’s ruling on the grounds that under 42 U.S.C. § 1395ddd(f)(3), the ALJ lacked jurisdiction to consider Safeguard’s determination that there had been a high level of payment error. Second, the MAC found that the original 99.85% error rate was sufficient to permit extrapolation of overpayments, and explained that the Medicare statute did not require its contractors to determine that there was high error rate before undertaking audits, which can include statistical sampling.

Balko appealed the MAC’s determination to Federal District Court which granted summary judgment in favor of the Secretary on December 28, 2012, upholding the MAC’s determination.

The United States Court of Appeals for the Third Circuit similarly upheld the district court’s ruling on the grounds that under 42 U.S.C. § 1395ddd(f)(3) it lacked jurisdiction to review the determination that there had been a high error rate. In addition, the court held that there was substantial evidence supporting the Secretary’s final decision. The Third Circuit Court of Appeals reasoned that it was required to abide by the clear language in the statute which reads, “There shall be no administrative or judicial review under Section 1395ff of this Title, Section 1395oo of this Title, or otherwise, of determinations by the Secretary of sustained or high levels of payment errors under this paragraph.” The Court cited as authority for its ruling the Court of Appeals for the District of Columbia Circuit’s decision that the statute
precludes a court of appeals review of the Secretary’s determination that there has been a high level of payment error. *Gentiva Healthcare Corp. v. Sebelius,* 723 F.3d. 292, 297 (D.C. Cir. 2013). The Court went on to note that Balko bore a heavy burden of showing that the sample was statistically invalid, and that Balko did not identify any portion of the record “which even hints that this conclusion was erroneous.”


On January 22, 2014, the United States District Court for the District of Nebraska granted a Motion for Summary Judgment in favor of HHS upholding the validity of a zone program integrity contractor’s (ZPIC) overpayment extrapolation. Schuldt was a healthcare provider that received Medicare reimbursement for chiropractic services. Wisconsin Physician Services (“WPS”) is a Medicare ZPIC that conducted an expanded post-payment medical review of claims submitted by Schuldt for chiropractic services furnished to 75 beneficiaries from January 2008 through March 2010. The review included a statistical sampling of 214 claims representing 445 services billed out of a universe of 5,098 services billed for 154 unique beneficiaries. WPS concluded that Schuldt had a 99.55% error rate equating to an actual overpayment of $11,376.13 for the 445 service claims submitted, which when extrapolated to the universe of claims, resulted in a total overpayment of $126,041.31. Schuldt appealed by filing both a redetermination and reconsideration request, both of which appeals held in favor of WPS’s decision.

Schuldt then appealed to the ALJ who found that 344 of the services billed were properly submitted and that Schuldt should be paid for them. Both Schuldt’s statistical expert and the ALJ’s own statistical expert concluded that “the methodology used by WPS was not reliable and should not be used for purposes of extrapolating the findings to a larger universe beyond the samples.” The experts “suggested that a larger sample of claims should have been used or samples should have been selected from a larger number of beneficiaries.”

The Medicare Appeals Counsel, on its own motion, conducted a *de novo* review of the ALJ’s decision on the issue of whether Schuldt met its burden of proving that the statistical sampling methodology used by WPS was invalid and insufficiently reliable to be used for the purpose of estimating an overpayment to a larger universe of claims. On November 2, 2012, the Medicare Appeals Counsel concluded that the ALJ erred in finding WPS’s sampling methodology and overpayment extrapolation to be invalid. *Id.*
On January 4, 2013, Schuldt appealed the case to the United States District Court for the District of Nebraska on the issue of whether the statistical sampling and extrapolation used by WPS was valid. The district court granted HHS’s motion for summary judgment noting that the Medicare Program Integrity Manual, Chapter 3, Section 3.10 allows for smaller statistical samples with less-precise results because contractors are directed to assess overpayments at the lower level of confidence intervals, giving the benefit of the doubt to the Medicare provider. The district court held that there was substantial evidence to support the MAC’s conclusion that the plaintiff failed to meet its burden of demonstrating that WPS’s sampling methodology and overpayment extrapolation were invalid. The court states in its opinion,

> The sampling methodology was based on a stratified random sample design, consistent with MPIM guidance. Schuldt presented no ‘evidence of a different sample from the universe of claims that yield[ed] a lower rate of denials or prove[d] that the projection [was] not a true estimate of the rate of denials in the non-sample universe.’…Neither did Schuldt ‘establish the validity of all or a sufficient number of its actual claims [in the non-sampling universe of claims] to demonstrate that the HHS projection [was] factually impossible of correctness.’…Neither of those tasks should have been onerous in this case, where WPS’s sampling methodology indicated that between 99.55% and 100% of services for which Schuldt claimed reimbursement through Medicare had been paid in error.

C.  


On July 16, 2013, the United States District Court for the District of Columbia granted a motion for summary judgment in favor of HHS confirming the validity of disallowance of Medicare bad debt held at an outside collection agency (OCA) during the fiscal year in which it was claimed by the hospital on its Medicare cost report. Lakeland Regional Health System attempted to claim Medicare bad debt allowances in its fiscal year 2005 cost report with respect to Medicare bad debts still placed at the hospital’s OCA. HHS denied the Medicare reimbursement for the bad debts on the grounds that the debts could not be “deemed uncollectable under 42 C.F.R. § 413.89(e) while pending at an outside collection agency.” Lakeland argued that HHS’s position constituted a change in policy in violation of 42 U.S.C. § 1395f, hereinafter referred to as the “Bad Debt Moratorium.”

In 1987, Congress enacted what is referred to as the “Bad Debt Moratorium” prohibiting the Secretary of HHS from making changes to
the agency’s bad debt policy in effect on August 1, 1987. At issue in the case is whether or not HHS complied with the Bad Debt Moratorium.

Lakeland provided covered services to Medicare beneficiaries during fiscal year 2005. Some of the beneficiaries failed to pay their hospital co-insurance and deductibles. Lakeland subsequently wrote the debts off as uncollectible and referred them to an outside collection agency. While collection efforts at the outside agency were still pending, Lakeland submitted its fiscal year 2005 cost report to its fiscal intermediary which included the bad debt write offs. The fiscal intermediary disallowed payments for debts that Lakeland sent to the outside collection agency. Lakeland appealed and argued that it had met the statutory criteria for bad debt reimbursement or, in the alternative, that the fiscal intermediary decision constituted a change in policy in violation of the bad debt moratorium.

The court ruled in favor of HHS that accounts pending at collection agencies cannot be written off as bad debts until collection activity has terminated. The court held that it was unnecessary for Medicare’s outside collection agency policy to be “explicitly set forth in a pre-moratorium writing.” The court states in its ruling, “The interpretive guidance in place on August 1, 1987 did not purport to be comprehensive review of all conditions that might be placed on reimbursement of Medicare bad debts…..” The court ruled that, where an OCA continues collection efforts on behalf of the provider, the provider may not claim that a bad debt is “actually uncollectible when claimed as worthless” or that “sound business judgment” would lead one to conclude that “there was no likelihood of recovery at any time in the future.”

Significantly, the court’s ruling conflicts with two previous rulings issued by the United States District Court for the District of Columbia with respect to bad debts claimed on a provider’s cost report that are placed at an OCA. In District Hosp. Partners v. Sebelius, Civ. Action No. 11-1717 (D.D.C. Mar. 26, 2013) and Foothill Hosp-Morris L. Johnston Mem’l v. Leavitt, 558 F. Supp. 2d 1, (D.D.C. 2008), the United States District Court for the District of Columbia ruled a Medicare contractor is not permitted to disallow Medicare bad debt solely on the grounds that the bad debt was still at an OCA. CMS did not appeal these two decisions to the Court of Appeals for the District of Columbia. However, Lakeland has appealed the district court’s decision to the United States Court of Appeals for the District of Columbia Circuit on this bad debt reimbursement issue related to OCAs. Hopefully the United States Court of Appeals for the District of Columbia will resolve this issue and provide clarity to providers.