A. Final Rules

1. CY 2014 Medicare Physician Fee Schedule Final Rule

- The MPFS Final Rule revises payment policies under the Medicare Physician Fee Schedule and makes other policy changes related to Medicare Part B payment, beginning January 1, 2014, unless otherwise noted.
- While many reimbursement and policy changes were addressed in the MPFS Final Rule, some of the more significant included the following:
  - **Payment Updates (78 Fed. Reg. 74397):**
    - Under the MPFS Final Rule CMS stated the conversion factor for CY 2014 would be $27.2006, but this was adjusted by the Pathway for SGR Reform Act of 2013 (Pub. Law 113-67, Dec. 26, 2013) which raised the conversion factor for CY 2014 to $35.8228.
    - The original conversion factor outlined in the MPFS Final Rule represented a decrease of 20.1% from CY 2013, which was less than the 24.4% decrease called for in the MPFS Proposed Rule.
    - The smaller reduction was due in part to a 4.72% adjustment to the conversion factor to offset the decrease in Medicare physician payments.

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1 Ross E. Sallade would like to thank all of the authors of the RAP Legal Alerts from 2013-2014 on which this outline was based. Each of the authors is given attribution credit in each relevant section of this outline.

2 Special thanks to Dan Hettich of King & Spalding LLP (Washington, D.C.) for authoring the original RAP Legal Alert, "CMS Issues Medicare Physician Fee Schedule Final Rule" on which this section of the outline was based.
that would otherwise have occurred due to the CY 2014 rescaling of the RVUs so that the proportions of total payments for the work, PE, and malpractice RVUs match the proportions in the final revised Medicare Economic Index (MEI) for CY 2014.

- The decrease was also due in part to application of the Sustainable Growth Rate (SGR). At the time the MPFS Final Rule was published CMS anticipated that Congress would intervene and repeal this decrease prior to the start of the CY 2014 as the President's budget calls for averted these cuts and the finding of a permanent solution to the SGR problem.
- CMS was correct as Congress passed the SGR Act – after the MPFS Final Rule was published. The new law prevented physician payment cuts from taking effect on January 1, 2014 and instead provided a 0.5% increase in payments through March 31, 2014. This increased the 2014 conversion factor to $35.8228.
- The SGR Act also called for a 2% annual reduction in fees through 2023.
- Because the SGR Act only included a 3 month patch on the SGR until March 31, 2014 it puts the onus on Congress to find a permanent solution to the SGR, and one that is budget neutral and does not rely upon deficit spending. This means Congress will have to make cuts elsewhere to sustain the SGR fix, which is estimated to cost between $120B and $170B.
- The current permanent SGR fix under consideration includes substantial payment changes, including shifting the payment formula from fee-for-service to pay for performance and would increase physician payments 0.5% each year until 2018, and then stay flat through 2023.

- **Revisions to the Medicare Economic Index** (78 Fed. Reg. 74264):

  - CMS finalized the proposed revisions to the calculation of the MEI in response to recommendations by a Technical Advisory Panel that met during CY 2012.
  - The MEI is the price index used to update physician payments for inflation and one of the factors used in determining the MPFS conversion factor, discussed above, along with the SGR.
  - The MPFS Final Rule includes changes in the MPFS RVUs assigned to the work and practice expense categories so that the weights used in the MPFS payment calculation will continue to mirror those in the MEI. As a result, some payment is being redistributed to work from practice expense.

- **Revisions to the Practice Expense Geographic Adjustment**, 78 Fed. Reg. 74380:

  - CMS adjusts payments under the MPFS to reflect the local cost of operating a medical practice as compared to the national average.
  - CMS calculates separate geographic practice cost indices (GPCIs) to adjust the work, practice expenses (PE), and malpractice cost components of each payment.
• CMS finalized new GPCIs using updated data consistent with the requirement that CMS review GPCIs every three years and adjust them as appropriate with a two-year phase-in.
• The updated GPCIs will be phased in over CY 2014 and CY 2015.

  o **Payment for Primary Care and Complex Chronic Care Management** (78 Fed. Reg. 74414):

    • CMS finalized its proposal begin making a separate payment for chronic care management services (non-face-to-face complex chronic care management services) for Medicare beneficiaries who have multiple, significant chronic conditions (two or more).
    • Chronic care management services include the development, revision, and implementation of a care plan; communication with the patient, caregivers, and other treating health professionals; and medication management.
    • Qualifying beneficiaries can choose a physician or other eligible practitioner to furnish these services over 30-day periods.
    • CMS indicates it will establish practice standards necessary to support payment for these care management services through future notice-and-comment rulemaking.
    • The additional payments will begin in CY 2015.

  o **Telehealth Services** (78 Fed. Reg. 74399):

    • In order to improve access to telehealth services in shortage areas, CMS finalized its proposal "to modify its regulations describing eligible telehealth originating sites to include health professional shortage areas located in rural census tracts of urban areas as determined by the Office of Rural Health Policy."
    • CMS indicated that determinations for geographic eligibility for an originating site for the entire calendar year will be made on an annual basis as of December 31st of the preceding year.
    • Per CMS, this change avoids mid-year changes to geographic designations (sometimes without advance notice to Medicare beneficiaries and providers) that could result in unexpected disruptions to established telehealth originating sites and avoid the need to make mid-year Medicare telehealth payment policy changes.
    • This change also enables sites within HPSAs in MSAs that have rural characteristics to qualify as originating sites and improve access to telehealth services in shortage areas.

  o **Application of Therapy Caps to Critical Access Hospitals** (78 Fed. Reg. 74406):

    • Consistent with the American Taxpayers Relief Act, CMS finalized its proposal to apply the "per beneficiary limits to outpatient therapy
services" to outpatient therapy services furnished in Critical Access Hospitals.

- Application of the caps applies to physical and speech language pathology services as well as to occupational therapy services.

- **Misvalued Codes (78 Fed. Reg. 74254):**
  - Consistent with amendments made by the Affordable Care Act, CMS identified and reviewed potentially misvalued codes and finalized values for around 200 codes and assigned interim final values for approximately 200 services, including services for hip and knee replacements, mental health services, and gastrointestinal endoscopy services.
  - CMS elected not to finalize its proposal to adjust relative values under the MPFS to effectively cap the physician practice expense payment for procedures furnished in a non-facility setting (e.g., physician office setting) at the total payment rate for the service when furnished in an ambulatory surgical center or hospital outpatient setting.
  - Instead, CMS indicated it will consider issues raised by public commenters and will address the issue in future rulemaking.

- **Compliance with State Law for Incident to Services (78 Fed. Reg. 74410):**
  - CMS required as a condition of payment that “incident to” services be furnished in compliance with applicable state law.
  - According to CMS this policy strengthened program integrity efforts by allowing CMS to deny or recoup payments when services are not furnished in compliance with state law.
  - CMS also consolidated the “incident to” requirements for all practitioners that are permitted to bill Medicare directly for their services, reducing regulatory redundancies and making it less difficult for practitioners to determine what is required in order to bill Medicare for “incident to” services.
  - The effective date for this portion of the MPFS Final Rule is March 3, 2014.

- **Physician Quality Reporting System (PQRS) (78 Fed. Reg. 74454):**
  - PQRS is a pay-for-reporting program that uses a combination of incentive payments and downward payment adjustments to promote reporting of quality information by eligible professionals (EPs). The program provides an incentive payment through 2014 to EPs and group practices who satisfactorily report data on quality measures for covered professional services. There were a multitude of changes to PQRS, some of which included the following:
• Retired several claims-based measures and added 57 new individual measures and 2 measure groups;
• Beginning in 2014, EPs may satisfy the PQRS by participating in a qualified clinical data registry, as permitted under the American Taxpayer Relief Act of 2012. Physician groups that reported PQRS measures for 2012 will have their results publicly reported on the Physician Compare website for 2014;
• Beginning in 2015, a downward payment adjustment will apply to EPs who do not satisfactorily report data on quality measures; and
• Finalized requirements for reporting PQRS measures as a group practice under the Group Practice Reporting Option (GPRO) using the registry, EHR, and GPRO web interface reporting mechanisms for the 2014 PQRS incentive. In some cases, the same criteria for satisfactory reporting under the GPRO apply for purposes of the 2014 PQRS incentive and the 2016 PQRS payment adjustment.

○ **Physician Value Payment Modifier** (78 Fed. Reg. 74757): In 2016, CMS will apply a Value-Based payment modifier to groups of 10 or more eligible professionals based on the group's performance under the PQRS. Only upward adjustments will apply to physician groups with between 10 and 99 eligible professionals. Physician groups with 100 or more eligible professionals will have both upward and downward modifiers applied as appropriate.

○ **EHR Incentive Program** (78 Fed. Reg. 74753): Among other changes, CMS finalized additional options for EPs to report clinical quality measures (CQMs) under the Medicare EHR Incentive Program beginning in 2014, including:

  ▪ Beginning in 2014 EPs can submit clinical quality measures (CQM) using qualified clinical data registries for purposes of meeting the CQM reporting component of meaningful use (MU) for the EHR Incentive Program; and
  ▪ Adding a group reporting option to the Medicare EHR Incentive Program beginning in CY 2014 for EPs who are part of a Comprehensive Primary Care Initiative (CPCI) practice site.

○ **Physician Compare Website** (78 Fed. Reg. 74446): The MPFS Final Rule outlines the next phase of the plan to publicly report physician performance information on Physician Compare. Some measures finalized included publicly reporting:

  ▪ all measures collected through the GPRO web interface for groups of all sizes participating in the 2014 PQRS GPRO and for ACOs participating in the Medicare Shared Savings Program;
  ▪ certain measures that groups report via registries and EHRs in 2014 under the PQRS GPRO; and
Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS) data for group practices of 100 or more eligible professionals reporting data in 2013 under the GPRO, and for ACOs participating in the Medicare Shared Savings Program.

- **Policies Regarding the Clinical Laboratory Fee Schedule** (78 Fed. Reg. 74440): CMS finalized its proposal to define technological changes as changes to the tools, machines, supplies, labor, instruments, skills, techniques, and devices by which laboratory tests are produced and used.

- **Medicare Coverage of Investigational Devices and Clinical Trials** (78 Fed. Reg. 74429):
  - CMS proposed significant modifications to its regulations governing Medicare coverage of investigational devices and the routine items and services furnished to beneficiaries during the clinical studies or trials conducted under the Food and Drug Administration Investigational Device Exemption regulations.
  - Those proposals included requiring that the principal purpose of a clinical study be to evaluate whether the item or service can meaningfully improve health outcomes and creating a centralized review process as opposed to utilizing local Medicare contractors.
  - Although these proposals were largely adopted, CMS did make multiple minor modifications to its proposal including changes to certain definitions.

- **The Outpatient Mental Health Treatment Limitation** (MLN Matters®Number: MM8533, December 20, 2013):
  - Beginning in CY 2014 CMS will pay 80% of the MPFS amount for outpatient mental health services, same as other Medicare Part B services.
  - This was implemented as a result of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 which required phasing out of the prior outpatient mental health treatment limitation over a 5-year period, from 2010-2014, under which CMS only paid 50% of the MPFS amount for outpatient mental health services.

- **Limit Medicare Physician Fee Schedule to Hospital Outpatient Setting and Ambulatory Surgical Center Payment Rate (NOT Finalized)**: CMS did NOT finalize its proposal to "adjust relative values under the PFS to effectively cap the physician practice expense payment for procedures furnished in a non-facility setting at the total payment rate for the service when furnished in an ambulatory surgical center or hospital outpatient setting."

For a copy of the MPFS Final Rule, see: [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html)
2. CY 2014 End Stage Renal Disease PPS; Durable Medical Equipment Prosthetics and Orthotics Final Rule

- The CMS released the "End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Final Rule" (ESRD Final Rule) in the Federal Register on December 2, 2013. See, 78 Fed. Reg. 72156.
- The ESRD Prospective Payment System (ESRD PPS) was established for the treatment of ESRD effective January 1, 2011, to be phased in over a four year period. During the transition, ESRD facility payment rates were based on a blend of the composite rate methodology and the new PPS rate for those ESRD facilities that did not elect to be paid 100 percent under the ESRD PPS starting on January 1, 2011. CY 2014 is the final year of the 4-year transition period. In 2014, all ESRD facilities must be paid 100 percent of the ESRD PPS rate for renal dialysis services furnished on or after January 1, 2014.
- Most provisions are effective on January 1, 2014, with limited exceptions that go into effect on April 1, 2014.
- The ESRD Final Rule updates and makes revisions to the ESRD PPS for CY 2014 and sets forth requirements for the ESRD quality incentive program (QIP), clarifies the grandfathering provision related to the 3-year minimum lifetime requirement (MLR) for Durable Medical Equipment (DME), and provides clarification of the definition of routinely purchased DME. The ESRD Final Rule also implements budget-neutral fee schedules for splints and casts, and intraocular lenses (IOLs) inserted in a physician’s office and makes a few technical amendments and corrections to existing regulations related to payment for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items and services.
- Highlights from this ESRD Final Rule include the following:
  - **Payment Updates** (78 Fed. Reg. 72158, 72160-):
    - CMS finalized a CY 2014, ESRD bundled market basket minus multi-factor productivity (MFP) increase factor of 2.8%, reflecting the CY 2014 market

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3 Special thanks to Isabella R. Edmundson (King & Spalding LLP, Atlanta, GA) for authoring the original RAP Legal Alert, "Publication of End-Stage Renal Disease Prospective Payment System Final Rule" on which this section of the outline was based.
basket increase of 3.2% minus the current forecast of the MFP adjustment of 0.4%.

- The ESRD Final Rule updated the ESRD PPS base rate to $239.02 for calendar year (CY) 2014, which represents a decrease from the CY 2013 base rate of $240.36. CMS did not, however, implement the much more drastic reduction it had proposed to a rate of $216.95.

- In part the reduction in the ESRD PPS base rate is attributable to the implementation of the Congressional direction under the American Taxpayer Relief Act to adjust ESRD rates to reflect the reduction in the use of drugs since 2007, and in this ESRD Final Rule CMS finalized the methodology for calculating the amount of the drug utilization adjustment. CMS indicates it is adopting a 3- to 4-year transition period for full implementation of the drug utilization reduction by offsetting the reduction by the payment update, that is the ESRD bundled market basket minus productivity increase factor, and other impacts (such as the outlier or training add-on, if applicable) to create an overall zero percent impact for all ESRD facilities from the previous year’s payments for CYs 2014 and 2015. For 2016 CMS will determine how to implement the balance of the reduction and adjustment factors. See, 78 Fed. Reg. 72161.

- The ESRD Final Rule adjusted the outlier service fixed-dollar amount for adult and pediatric ESRD patients. For pediatric patients, the fixed-dollar loss amount increased from $47.32 to $54.01 and the adjusted average outlier services Medicare Allowable Payments (MAPs) decreased from $41.39 to $40.49. For adult beneficiaries, the fixed-dollar loss amount decreased from $110.22 to $98.67 and the adjusted average outlier services MAP amount decreased from $59.42 to $50.25. See, 78 Fed. Reg. 72179.

- The ESRD Final Rule also discusses the application of ICD-10-CM Diagnoses codes to the comorbidity payment adjustment codes. Effective October 1, 2014, CMS will implement the tenth revision of the ICD coding scheme. Accordingly, the ESRD Final Rule provides a crosswalk from ICD-9-CM to ICD-10-CM for codes that are subject to the comorbidity payment adjustment. See, 78 Fed. Reg. 72174.

- CMS finalized a 50% increase to the home dialysis training add-on payment adjustment that is made for both peritoneal dialysis and home hemodialysis training treatments. See, 78 Fed. Reg. 72182.

- CMS estimates that the ESRD Final Rule will not result in any overall change in total payments to ESRD facilities, although hospital-based facilities will see a 0.8% increase in payments.

- **ESRD Quality Incentive Program (QIP)** (78 Fed. Reg. 72188): The ESRD Final implemented requirements for the ESRD QIP – creating incentives for ESRD facilities to improve the quality of patient care delivered. Among other things, CMS added, revised, and expanded measures for the ESRD QIP (finalized 11 measures addressing infections, anemia management, dialysis adequacy, vascular access, mineral metabolism management, and patient experience of care). CMS finalized the method for calculating performance scores -- by weighting clinical measures at 75%
of the total performance score and weighting the reporting measures at 25%. The ESRD QIP will reduce payments to ESRD facilities that do not meet or exceed certain performance standards. CMS established CY 2014 as the performance period for QIP payment year 2016. For the ESRD QIP, CMS expects that in payment year 2016, total payments will be reduced by approximately $15.1 million.

- **Durable Medical Equipment, Prosthetics, Orthotics, and Supplies** (78 Fed. Reg. 72224, 72234, 72238): The ESRD Final Rule provided clarification on the definition of routinely purchased durable medical equipment (DME) and on the grandfathering provision of the DME three-year minimum lifetime requirement. CMS noted that the health care industry and beneficiaries have come to rely on items that qualified as DME prior to January 1, 2012 regardless of whether those items met the three-year minimum lifetime requirement set forth in section 414.202. Accordingly, CMS will not reopen those prior decisions and reclassify the equipment in light of the new three-year standard. CMS also implemented budget-neutral fee schedules for splints and casts and intraocular lenses inserted in a physician's office.

- For a copy of the ESRD PPS Final Rule, see: [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices-Items/CMS-1526-F.html?DLPage=1&DLSort=3&DLSortDir=descending](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices-Items/CMS-1526-F.html?DLPage=1&DLSort=3&DLSortDir=descending)
- For a copy of the RAP legal alert regarding the ESRD Final Rule, see: [http://www.healthlawyers.org/Members/PracticeGroups/RAP/emailalerts/Pages/PublicationofEnd-StageRenalDiseaseProspectivePaymentSystemFinalRule.aspx#sthash.JYDqUTOt.dpuf](http://www.healthlawyers.org/Members/PracticeGroups/RAP/emailalerts/Pages/PublicationofEnd-StageRenalDiseaseProspectivePaymentSystemFinalRule.aspx#sthash.JYDqUTOt.dpuf)

3. **CY 2014 Home Health Agency Prospective Payment System Final Rule**


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4 Special thanks to Lauren E. Slive (King & Spalding LLP, Atlanta, GA) for authoring the original RAP Legal Alert, "Publication of Home Health Prospective Payment System Final Rule" on which this section of the outline was based.
In part, the HHA Final Rule updates the HHA PPS rates, establishes rebasing adjustments, with a 4-year phase-in; removes 170 diagnosis codes within the HH PPS Grouper; and establishes home health quality reporting requirements for CY 2014 payment and subsequent years.

The provisions in the Final Rule are effective on January 1, 2014.

Highlights from this HHA Final Rule include the following:

Payment Updates.

1. **General (78 Fed. Reg. 72260-, 72293-):**
   - The HHA Final Rule reduces payments under the Home Health PPS by 1.05%, resulting in an estimated $200 million in decreased payments to home health agencies in calendar year (CY) 2014.
   - The decrease reflects the combined effects of the 2.3% HH payment update percentage ($440 million increase), the rebasing adjustments to the national, standardized 60-day episode payment rate, the national per-visit payment rates, and the NRS conversion factor ($520 million decrease), and the effects of ICD-9-CM HH PPS Grouper refinements ($120 million decrease).

2. **Diagnosis Codes (78 Fed. Reg. 72261).** The HHA Final Rule removed 170 diagnosis codes from diagnosis groups within the Home Health PPS Grouper.

3. **ICD-10-CM Application (78 Fed. Reg. 72260, 72271-):** On October 1, 2014, CMS will begin the use of ICD-10-CM codes within the Home Health PPS Grouper, in place of the existing ICD-9-CM codes used to report medical diagnoses and inpatient procedures.

4. **Rebasing Under the ACA (78 Fed. Reg. 72260, 72276):** As required by the Affordable Care Act (ACA), the standardized 60-day episode payment amount, the national per-visit rates, and the Nonroutine Medical Supply conversion factor will be rebased over the next four years. CMS is required by the ACA to limit the phase in of these adjustments over a four-year period in equal increments, not to exceed 3.5% of the amount in effect as of the date of enactment of the ACA, and to fully implement the rebasing adjustments by CY 2017. As part of the rebasing effort, CMS calculated the following beginning in 2014:
   - **Rebasing the Episode Rate:** an annual reduction to the national, standardized 60-day payment rate as $80.95 (CY 2010 payment rate of $2,312.94 x 0.035 = $80.95), to be applied equally each year from CY 2014 through CY 2017.
   - **Rebasing Per-Visit Amounts:** the six per-visit payment rates for each year from CY 2014 through CY 2017 will be increased as follows: Skilled Nursing, $3.96; Home Health Aide, $1.79; Physical Therapy, $4.32;
Occupational Therapy, $4.35; Speech-Language Pathology, $4.70; and Medical Social Services, $6.34.

- **Rebasing Other Components of the HH PPS:** CMS finalized a non-routine medical supplies (NRS) conversion factor of -2.82% each year for CY 2014 through CY 2017, and three separate Low Utilization Payment Adjustment add-on factors for skilled nursing, physical therapy, and speech-language pathology.

- **Home Health Quality Reporting and Surveys (78 Fed. Reg. 72297-):**
  - The Home Health Final Rule adds a requirement for HHAs to report two new claims-based quality measures for patients hospitalized during the first 30 days of a home health stay: (1) re-hospitalizations, and (2) emergency department use – thereby targeting unnecessary hospital readmission rates and preventable trips to the emergency department.
  - The Final Rule also reduces the number of home-health quality measures currently reported by home health agencies.
  - CMS will continue to work on the home health study, required by the ACA, which will assess the costs associated with providing access to care to patients with high severity of illness, low income patients, and/or patients in medically underserved areas.
  - **Outcome & Assessment Information Set (OASIS) Updates:** CMS finalized a rule to continue requiring the filing of OASIS data, claims data, and patient experience of care data to measure home health care quality for the annual payment update in 2014 and each following year.

- For a copy of the RAP legal alert regarding the HHA PPS Final Rule, see: [http://www.healthlawyers.org/Members/PracticeGroups/RAP/emailalerts/Pages/PublicationofHomeHealthProspectivePaymentSystemFinalRule.aspx](http://www.healthlawyers.org/Members/PracticeGroups/RAP/emailalerts/Pages/PublicationofHomeHealthProspectivePaymentSystemFinalRule.aspx)

**B. Important Reimbursement and Payment Developments of 2013-2014**

1. **2014 OIG Work Plan**

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5 Special thanks to Kippy Wroten of (Wroten & Associates Inc., Irvine, CA,) and Joseph M. Kahn (Nexsen Pruett PLLC, Raleigh, NC) for authoring the original Legal Alert, "OIG Releases 2014 Work Plan," on

The Work Plan sets forth current and ongoing projects to be addressed by the OIG during the fiscal year through the Office of Audit Services, Office of Evaluation and Inspections, Office of Investigations, and Office of Counsel to the Inspector General.

The Work Plan includes projects planned in each of the following: the Centers for Medicare & Medicaid Services; the public health agencies; the Administrations for Children & Families; and Administration on Aging. Information is also provided on projects related to issues that cut across departmental programs, including State and local government use of Federal funds, as well as the functional areas of the Office of the Secretary of Health & Human Services (HHS).

In evaluating proposals to include in the Work Plan, the OIG indicates that it will consider a number of factors, including the following:

- mandatory requirements for OIG reviews, as set forth in laws, regulations, or other directives;
- requests made or concerns raised by Congress, HHS management, or the Office of Management and Budget (OMB);
- top management and performance challenges facing HHS;
- work to be performed in collaboration with partner organizations;
- management’s actions to implement our recommendations from previous reviews; and
- timeliness.

A review of the annual Work Plan can provide insight into anticipated OIG initiatives for the upcoming year.

Overview of the 2014 Work Plan: Overall, there are a substantial number of new items included in the 2014 Work Plan, as well recurring items lagging over from 2013 and before. While a listing of each is of these items would be redundant of the plan itself, the following represents selected new and recurring areas that may be of interest:

- **Hospitals:**
  - **Selected New Items:** new inpatient admission criteria; Medicare costs associated with defective medical devices; analysis of salaries included in hospital cost reports; comparison of provider-based and free-standing clinics; outpatient evaluation and management services billed at the new-patient rate; and oversight of hospital privileging.
  - **Selected Recurring Items of Interest:** impact of provider based status on Medicare billing.
- **Nursing Homes:**
  - **Selected New Items:** Medicare Part A billing; and questionable billing patterns for Part B services during nursing home stays.
  - **Selected Recurring Items of Interest:** Questionable billing patterns for Part B services during nursing home stays.

- **Hospice:**
  - **Selected New Items:** Hospice in assisted living facilities and general inpatient facilities.
  - **Selected Recurring Items of Interest:** Hospice general inpatient care.

- **Medical Equipment and Supplies:**
  - **Selected New Items:** reasonableness of Medicare’s fee schedule amounts for selected medical equipment items compared to amounts paid by other payers; power mobility devices—lump-sum purchase versus rental; and competitive bidding for diabetes testing supplies.
  - **Selected Recurring Items of Interest:** diabetes testing supplier compliance with payment requirements for blood glucose test strips and lancets and effectiveness of system edits to prevent inappropriate payments for blood-glucose test strips and lancets to multiple suppliers.

- **Other Providers and Suppliers:**
  - **Selected New Items:** ambulance services portfolio report on Medicare Part B payments; rural health clinics – compliance with location requirements; portable X-ray equipment compliance with transportation and setup fee requirements; and Mental health providers—Medicare enrollment and credentialing.
  - **Selected Recurring Items of Interest:** ambulance services—questionable billing, medical necessity, and level-of-transport; ambulatory surgical center payment system; end-stage renal disease facility payment system for rental dialysis services and drugs; evaluation and management services—inappropriate payments; laboratory tests—billing characteristics and questionable billing; physicians and suppliers—noncompliance with assignment rules and place-of-service coding errors; sleep disorder clinics—high utilization of sleep-testing procedures; and Physical therapists—High utilization of outpatient physical therapy services.

- **Prescription Drugs; Part D – Prescription Drug Program:**
  - **Selected New Items:** manufacturer reporting of average sales prices for Part B drugs; Medicare Part B payments for drugs purchased under the
340B Program; payment for compounded drugs under Part B; comparison of Medicare Part D and Medicaid pharmacy reimbursement and rebates; and documentation of Part D drug event data.

- **Selected Recurring Items:** Comparison of average sales prices to average manufacturer prices

- **Other Part A and Part B Program Management Issues:**

  - **Selected New Items:** N/A
  - **Selected Recurring Items:** Enhanced enrollment screening process for Medicare providers; and Improper Medicare payments for beneficiaries with other insurance coverage.

- While additional detail on these foci can be found in the Work Plan itself, a few of those that may be of particular interest and merit additional detail in this outline include the following:

  - **Hospital - New inpatient admission criteria: Policies and Practices.** The OIG will determine the impact of new inpatient admission criteria on hospital billing, Medicare payments, and beneficiary payments. The review will also determine how billing varied among hospitals in FY 2014. Context—Previous OIG work found overpayments for short inpatient stays, inconsistent billing practices among hospitals, and financial incentives for billing Medicare inappropriately. Beginning in FY 2014, new criteria state that physicians should admit for inpatient care those beneficiaries who are expected to need at least 2 nights of hospital care. Beneficiaries whose care is expected to last less than 2 nights should be treated as outpatients. The criteria represent a substantial change in the way hospitals bill for inpatient and outpatient stays.

  - **Hospital - Impact of provider-based status on Medicare billing: Policies and Practices.** The OIG will determine the impact of subordinate facilities in hospitals billing Medicare as being hospital based (provider based) and the extent to which such facilities meet CMS’s criteria. Context—Provider-based status allows a subordinate facility to bill as part of the main provider. Provider-based status can result in additional Medicare payments for services furnished at provider-based facilities and may increase beneficiaries’ coinsurance liabilities. In 2011, the Medicare Payment Advisory Commission (MedPAC) expressed concerns about the financial incentives presented by provider-based status and stated that Medicare should seek to pay similar amounts for similar services.

  - **Hospital - Comparison of provider-based and free-standing clinics (new): Policies and Practices.** The OIG will review and compare Medicare payments for physician office visits in provider-based clinics and free-standing clinics to determine the difference in payments made to the clinics for similar procedures and assess the potential impact on the Medicare program of hospitals’ claiming provider-based status for such facilities. Context—Provider-based facilities often
receive higher payments for some services than do freestanding clinics. The requirements to be met for a facility to be treated as a provider-based facility are at 42 CFR § 413.65(d).

- **Medicare Part A billing by skilled nursing facilities - Policies and Practices.** The OIG will describe SNF billing practices in selected years and will describe variation in billing among SNFs in those years. Context—Prior OIG work found that SNFs increasingly billed for the highest level of therapy even though beneficiary characteristics remained largely unchanged. OIG also found that SNFs billed one-quarter of all 2009 claims in error, resulting in $1.5 billion in inappropriate Medicare payments. CMS has made substantial changes to how SNFs bill for services for Medicare Part A stays.

- **Hospice - Hospice in assisted living facilities: Policies and Practices.** The OIG will review the extent to which hospices serve Medicare beneficiaries who reside in assisted living facilities (ALFs). The OIG will determine the length of stay, levels of care received, and common terminal illnesses of beneficiaries who receive hospice care in ALFs. Context—Pursuant to the Affordable Care Act, § 3132, CMS must reform the hospice payment system, collect data relevant to revising hospice payments, and develop quality measures for hospices. The OIG's work is intended to provide HHS with information relevant to these requirements. Medicare covers hospice services for eligible beneficiaries under Medicare Part A. (Social Security Act, § 1812(a).) Hospice care may be provided to individuals and their families in various settings, including the beneficiary’s place of residence, such as an ALF. ALF residents have the longest lengths of stay in hospice care. The Medicare Payment Advisory Commission has said that these long stays bear further monitoring and examination.

- **Hospice - Hospice general inpatient care: Quality of Care and Safety.** The OIG will review the use of hospice general inpatient care and assess the appropriateness of hospices’ general inpatient care claims and the content of election statements for hospice beneficiaries who receive general inpatient care. We will also review hospice medical records to address concerns that this level of hospice care is being misused. Context—Hospice care is palliative rather than curative. When a beneficiary elects hospice care, the hospice agency assumes the responsibility for medical care related to the beneficiary’s terminal illness and related conditions. Federal regulations address Medicare conditions of participation for hospices. (42 CFR Part 418.) Beneficiaries may revoke their election of hospice care and return to standard Medicare coverage at any time. (42 CFR § 418.28.)

- **Home Health - Home health prospective payment system requirements: Billing and Payments.** The OIG will review compliance with various aspects of the home health prospective payment system (PPS), including the documentation required in support of the claims paid by Medicare. The OIG will determine whether home health claims were in paid in accordance with Federal laws and regulations.
Context—A prior OIG report found that one in four HHAs had questionable billing. Further, CMS designated newly enrolling HHAs as high-risk providers, citing their record of fraud, waste, and abuse. Since 2010, nearly $1 billion in improper Medicare payments and fraud has been identified relating to the home health benefit. Some beneficiaries who are confined to their homes are eligible to receive home health services. (Social Security Act, §§ 1835(a)(2)(A) and 1861(m).) Such services include part-time or intermittent skilled nursing care, as well as other skilled care services, such as physical, occupational, and speech therapy; medical social work; and home health aide services.

- **Laboratory tests**—Billing characteristics and questionable billing. Billing and Payments. The OIG will review billing characteristics for Part B clinical laboratory (lab) tests and identify questionable billing. Context—Medicare is the largest payer of clinical lab services in the Nation. Medicare’s payments for lab services in 2008 represented an increase of 92 percent over payments in 1998. In 2010, Medicare paid about $8.2 billion for lab tests, accounting for 3 percent of all Medicare Part B payments. Much of the growth in lab spending has resulted from the increased volume of ordered services. Part B covers most lab tests and pays 100 percent of allowable charges; Medicare beneficiaries do not pay copayments or deductibles for lab tests. Medicare should pay only for those lab tests that are ordered by a physician or qualified nonphysician practitioner who is treating a beneficiary. (42 CFR § 410.32(a))

- **Part B payments for drugs purchased under the 340B Program.** Policies and Practices. The OIG will determine how much Medicare Part B spending could be reduced if Medicare were able to share in the savings for 340B-purchased drugs. The OIG will calculate the amount by which ASP-based payments exceed 340B prices and estimate potential savings on the basis of various shared-benefit methodologies. Context—Previous OIG work revealed that some Medicaid State agencies have developed strategies to take advantage of the discounts on 340B drugs. The 340B Program requires drug manufacturers to provide discounted outpatient drugs to approximately 10,000 covered entities. Medicare Part B reimburses for almost all covered outpatient drugs (including those purchased by 340B entities) on the basis of the average sales price (ASP), regardless of the amount paid for the drug. Medicare Part B providers that purchase drugs under the 340B program can fully retain the difference between the ASP-based payment amount and the 340B purchase price.

- **Enhanced enrollment screening process for Medicare providers.** Provider Eligibility. The OIG will determine the extent to which and the way in which CMS and its contractors have implemented enhanced screening procedures for Medicare providers pursuant to the Affordable Care Act, § 6401. The OIG will also collect data on and report the number of initial enrollments and enrollment revalidations approved and denied by CMS before and after the implementation of the enhanced screening procedures. Context—As part of an effort to prevent fraud, waste, and abuse resulting from vulnerabilities in the Medicare enrollment
process, CMS is implementing new authorities that include a site visit process, an automated provider screening process, fingerprinting, and background checks.

- For a copy of the RAP legal alert, jointly published with the Fraud and Abuse Practice Group, see: [http://www.healthlawyers.org/Members/PracticeGroups/FA/EmailAlerts/Pages/OIGReleases2014WorkPlan.aspx](http://www.healthlawyers.org/Members/PracticeGroups/FA/EmailAlerts/Pages/OIGReleases2014WorkPlan.aspx)

2. **FY2015 Department of Health and Human Services Budget for CMS.**

- On March 4, 2014, the Department of Health and Human Services released its FY2015 Budget.
- While the budget includes all of DHHS, of significant interest is the budget for CMS and Medicaid.
- The FY budget estimate for CMS is $897.3B, a net increase of $54.3B above the FY2014 budget.
- Of interest to many practitioners are the legislative proposals included by DHHS in the budget itself. While these are just legislative proposals, they do provide valuable insight to what we can expect to see in regards to regulatory and reimbursement proposals over the upcoming year, and longer. According to DHHS, these proposals are projected to save $407.2B over the next decade "by more closely aligning payments with costs of care, strengthening provider payment incentives to promote high-quality efficient care and making structural changes that will reduce federal subsidies to high-income beneficiaries and create incentives for beneficiaries to seek high-value services."
- While there are many legislative proposals included in the CMS portion of the DHHS budget, some of the more intriguing include the following:
  - **Reduce Medicare Coverage of Bad Debts:** Medicare currently reimburses 65% of bad debts resulting from beneficiaries’ non-payment of deductibles and coinsurance after providers have made reasonable efforts to collect the unpaid amounts. Starting in 2015, this proposal would reduce bad debt payments to 25% over 3 years for all providers.
  - **Critical Access Hospital Proposals:** beginning in 2015
    - **Proposal 1:** reduce CAH reimbursement to 100% of costs rather than the 101% of reasonable costs currently enjoyed by CAHs.
    - **Proposal 2:** Prohibit CAHs from maintaining or obtaining designations as CAHs when they are less than 10 miles from the nearest hospital. Those losing CAH status would be paid under the IPPS or other applicable system.
  - **Adjust Payment Updates for Certain Post-Acute Care Providers:** Reduces market basket updates for IRFs, LTCHs, and HHAs by 1.1% points in each year 2015 through 2024. And reduce market basket updates for SNFs under an accelerated
schedule, beginning with a -2.5% update in FY2015 down to a -0.97% update in FY2022.

- **Encourage Appropriate Use of Inpatient Rehabilitation Facilities:** Beginning in 2015, adjust the standard for classifying a facility as an IRF to reinstate the requirement that 75%, rather than the current 60%, of patient cases admitted to an IRF meet one or more of 13 designated severity conditions.

- **Modernize Payments for Clinical Laboratory Services:** Lower the payment rates under the Clinical Laboratory Fee Schedule by -1.75% every year from 2016 through 2023.

- **Modify Reimbursement for Part B Drugs:** Beginning in 2015 lower payment for drugs reimbursed under Medicare Part B from 106% of the Average Sales Price (ASP) to 103% of ASP, with an exception for instances where a physician’s cost for purchasing the drug exceeds ASP + 3%, in which case the manufacturer would be required to provide a rebate such that the net cost to the provider to acquire the drug equals ASP + 3% minus a standard overhead fee.

- **Exclude Certain Services from the In-Office Ancillary Services Stark Exception:** Effective calendar year 2016, this proposal would encourage more appropriate use of ancillary services by amending the in-office ancillary services exception under Stark to prohibit certain referrals for radiation therapy, therapy services, advanced imaging, and anatomic pathology services except in cases where a practice meets certain accountability standards. DHHS indicates this is driven in part on evidence suggesting that this exception may have resulted in overutilization and rapid growth of certain services.

- **Implement Value-Based Purchasing for Additional Providers:** This proposal would implement value-based purchasing program for SNFs, HHAs, ASCs, and hospital outpatient departments, beginning in 2016, and would require at least 2% of payments be tied to the quality and efficiency of care.

- For a copy of the FY 2015 Dept. Health and Human Services Budget, see: [http://www.hhs.gov/budget/#brief](http://www.hhs.gov/budget/#brief)
- For a copy of the Dept. of Health and Human Services press release accompanying the FY 2015 Budget, see: [http://www.hhs.gov/secretary/about/speeches/sp20140304.html](http://www.hhs.gov/secretary/about/speeches/sp20140304.html)
- For a copy of the video press release and comments from Kathleen Sebelius, see: [https://www.youtube.com/watch?v=eCebhJwZfUM](https://www.youtube.com/watch?v=eCebhJwZfUM)
- A copy of the RAP legal alert regarding the FY 2015 Dept. Health and Human Services Budget was not available at the time this outline was finalized. However, a copy can be found at the RAP Home Page for Legal Alerts at: [http://www.healthlawyers.org/Members/PracticeGroups/RAP/emailalerts/Pages/default.aspx](http://www.healthlawyers.org/Members/PracticeGroups/RAP/emailalerts/Pages/default.aspx)

### 3. Clarification on Home Health Face-to-Face Encounters.6

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6 Special thanks to Hilary L. Isacson, JD, MPH (Sutter Health, Sacramento, CA), for authoring the original RAP Legal Alert, "CMS Clarifies Documentation Requirements for Home Health Face-to-Face Encounters" on which this section of the outline was based.

The requirement arises under 42 C.F.R. §424.22(a)(1)(v), which provides as follows: "The physician responsible for performing the initial certification must document that the face-to-face patient encounter, which is related to the primary reason the patient requires home health services, has occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care by including the date of the encounter, and including an explanation of why the clinical findings of such encounter support that the patient is homebound and in need of either intermittent skilled nursing services or therapy services . . . ."

The article offers additional details on what CMS expects from ordering and certifying physicians and non-physician practitioners (NPPs), with examples of acceptable and unacceptable documentation.

CMS notes that the majority of home health payment errors are a result of insufficient documentation, such as face-to-face visit notes that simply list the patient's diagnoses and conclude that the patient is homebound.

CMS stresses that the narrative of the face-to-face encounter must draw a clear connection between the physician's clinical findings and the reasons for the patient's homebound status and need for skilled services.

As indicated by CMS in the article, "incorrect" documentation does not describe why the patient's clinical condition requires specific skilled services, and uses only boilerplate language or general phrases such as "taxing effort to leave home" to support homebound status.

Accordingly, rather than rely solely on forms based on lists and checkboxes, physicians and NPPs must explain the following two items in the face-to-face narrative, as required elements:

- **Confined to the Home**, i.e., to qualify for HHA services the patient must be homebound and the narrative must indicate why the patient is homebound; and
- **Need for Skilled Services**, i.e., to qualify for HHA services the patient must need intermittent skilled nursing services, physical therapy or speech language pathology, and the narrative must indicate which of these services will be performed in the home to treat the patient's medical condition(s).

CMS also recommends that all face-to-face narratives be identified as such, even when physicians and NPPs include them in other types of documentation, such as progress notes and hospital discharge summaries.


A copy of the RAP legal alert, "CMS Clarifies Documentation Requirements for Home Health Face-to-Face Encounters," see: [http://www.healthlawyers.org/Members/PracticeGroups/RAP/emailalerts/Pages/CMSClarifiesDocumentationRequirementsforHomeHealthFace-to-FaceEncounters.aspx](http://www.healthlawyers.org/Members/PracticeGroups/RAP/emailalerts/Pages/CMSClarifiesDocumentationRequirementsforHomeHealthFace-to-FaceEncounters.aspx)
C. Selected Reimbursement and Payment Case Law Developments of 2013-2014

1. Disproportionate Share Hospital (DSH) Cases:

   - This past year saw two cases weighing in on the application of dual eligibles as they relate to the computation of the Medicare DSH adjustment. Those two cases, discussed separately below, included Metropolitan Hospital vs. HHS, et al., and U.S. Department of Health & Human Services (HHS) in Catholic Health Initiatives v. Sebelius

   a. Metropolitan Hospital v. United States Department of Health and Human Services; Kathleen Sebelius, Secretary of the United States Department of Health and Human Services Nos. 11-2465/2466 (6th Cir. March 27, 2013)7

      - On March 27, the U.S. Court of Appeals for the 6th Circuit issued an opinion in Metropolitan Hospital vs. HHS, et al., regarding the interpretation of 42 C.F.R. Section 412.106(b).

      - At issue was whether patients dually eligible for Medicare and Medicaid whose Medicare Part A benefit was exhausted remained "entitled" to Part A for purposes of computation of the Medicare disproportionate share hospital (DSH) adjustment. Among other things, the court's ruling:
        o Reversed the ruling of the District Court declaring the U.S. Department of Health & Human Services (HHS) regulation invalid because it violates the statute it purports to implement; and
        o Remanded the case with instruction to enter judgment in favor of HHS.

Prior Proceedings

   - The District Court ruled that the regulation is invalid because it violates the statute that it purports to implement. Specifically, the District Court invalidated the regulation to the extent that it requires inclusion of inpatient days for patients not entitled to Medicare Part A benefits in the Medicare fraction (SSI ratio) of the DSH calculation.
   - In addition, the District Court invalidated the regulation to the extent that it calls for exclusion from the Medicaid fraction days attributable to such patients who were eligible for Medicaid but not entitled to Medicare Part A.
   - HHS appealed to the 6th Circuit and Metropolitan Hospital (Metro) filed a cross-appeal.

The Court of Appeals Decision

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7 Special thanks to Lauraine Palm Singh, Esquire (Singh Advisors LLC, Twin Cities, MN), for authoring the original RAP Legal Alert, "Metropolitan Hospital v. United States Department of Health and Human Services; Kathleen Sebelius, Secretary of the United States Department of Health and Human Services" on which this section of the outline was based.
The 6th Circuit reversed the judgment of the District Court and remanded the case with instruction to enter judgment in favor of HHS. Metro's cross-appeal was dismissed as moot. In so doing, the 6th Circuit specifically cited the following:
  o Congress has not "directly spoken" to how the regulation's "disproportionate patient percentage" (DPP) calculation should account for dual-eligible exhausted benefit days; and
  o The HHS Secretary's interpretation of the DPP provision is a permissible construction of 42 U.S.C. Section 1395ww.

Importance of this Decision

- Many cases presenting this issue are pending at the Provider Reimbursement Review Board, and thus the ultimate outcome of this line of cases will have a major impact to hospitals nationwide.

- For a complete copy of the legal alert and additional information on this case, see: http://www.healthlawyers.org/Members/PracticeGroups/RAP/emailalerts/Pages/MetropolitanHospitalvUSDepartmentofHealthandHumanServices.aspx#sthash.lc2WK2e3.dpuf


- On June 11, the U.S. Court of Appeals for the District of Columbia decided the appeal of the U.S. Department of Health & Human Services (HHS) in Catholic Health Initiatives v. Sebelius, No. 12-5092, regarding the exclusion of dual-eligible patient days in the Medicaid fraction when calculating the disproportionate patient percentage (DPP) that applies to a hospital's disproportionate share hospital (DSH) adjustment.
- At issue was the interpretation of the "entitled to benefits under Part A" phrase in the Medicare statute and the alleged retroactive application of this interpretation to a 1997 cost-reporting period. The dispute involved the placement of dual-eligible patient days into the Medicare versus Medicaid fraction when calculating DSH adjustments.
- The Court of Appeals reversed the district court and upheld HHS' interpretation of the phrase "entitled to benefits under Part A" resulting in the continuation of dual eligibles being placed in the Medicare fraction for calculation of DSH adjustments.
- The court also held that there was no impermissible retroactive application.
- As discussed above, the U.S. Court of Appeals for the 6th Circuit recently reached a similar holding in Metropolitan Hospital v. Sebelius.

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8 Special thanks to Stephanie M. Barr, Esquire (Marshall Dennehey Warner Coleman and Goggin PC, Philadelphia, PA), for authoring the original RAP Legal Alert, "D.C. Circuit Joins Sixth Circuit in Decision Regarding DSH Exhausted Part A Days: Catholic Health Initiatives v. Sebelius, D.C.Cir." on which this section of the outline was based.
**Court of Appeals Decision**

- The Court of Appeals noted the "Medicare statute's inconsistent and specialized use of the phrase 'entitled to benefits under Part A'" and concluded that both the hospital's and HHS' interpretations of the phrase were permissible. Therefore, following the analysis set forth in *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 476 U.S. 837, 842-43 (1984), which held that a where a statute is silent or ambiguous on an issue if the agency interpretation is permissible, the agency interpretation will be given deference, the court deferred to HHS' construction of the phrase in the Medicare statute.

**Importance of this Decision**

- A higher DPP means greater reimbursement for a hospital because the hospital would be servicing more low-income patients. If the dual-eligible exhausted days are excluded from the Medicaid numerator, the Medicaid fraction will go down and arguably for most hospitals the Medicare fraction will go up, resulting in a lower DPP.
- As there are many providers with individual and group appeals before PRRB on this issue and the decision potentially lowers reimbursement, this decision will be significant for hospitals.
- For a complete copy of the legal alert and additional information on this case, see: [http://www.healthlawyers.org/Members/PracticeGroups/RAP/emailalerts/Pages/DC CircuitJoinsSixthCircuitinDecisionRegardingDSHExhaustedPartADaysCatholicHealthInitiativesvSebelius,DC Cir.aspx#sthash.s365rjM.dpuf](http://www.healthlawyers.org/Members/PracticeGroups/RAP/emailalerts/Pages/DC CircuitJoinsSixthCircuitinDecisionRegardingDSHExhaustedPartADaysCatholicHealthInitiativesvSebelius,DC Cir.aspx#sthash.s365rjM.dpuf)

2. **Conditions of Payment vs. Conditions of Participation**


- This case arose following claims from a Relator and the United States that MedQuest submitted false claims stemming from two actions: (1) conducting diagnostic imaging tests without the required and appropriate physician supervision and (2) using another Medicare vendor’s billing number.
- The District Court granted summary judgment in favor of the Relator and United States and MedQuest appealed to the 6th Circuit. More specifically, the District Court's granting of summary judgment applied to both claims on the theory that MedQuest violated the federal False Claims Act both expressly and impliedly by submitting claims to the Medicare program certifying compliance with Medicare regulations that it was in fact not in compliance with.

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9 Special thanks to Martha Legg Miller, Esquire (Balch & Bingham LLP, Birmingham, AL), for authoring the original RAP Legal Alert, "Sixth Circuit Rules Physician Supervision Rules Pertaining to IDTFs are not Conditions of Payment and Reverses the District Court's Judgment" on which this section of the outline was based.
The 6th Circuit Court of Appeals reversed the District Court's granting of summary judgment, stating: "The regulatory scheme does not support FCA liability for failure to comply with the supervising-physician regulations, and the district court’s grant of summary judgment against MedQuest on this issue must be reversed. With respect to the second set of claims, MedQuest’s failure to satisfy the enrollment regulations and its use of a billing number belonging to a physician’s practice it controlled do not trigger the hefty fines and penalties created by the FCA. Summary judgment on this set of claims must also be reversed."

The 6th Circuit distinguished between "rules pertaining to roles and duties of supervising physicians at IDTFs and to additional certifications required for contrast testing procedures," which it found in 42 C.F.R. Section 410.33, from the reasonable and necessary standard set forth at 42 C.F.R. Section 410.32.

In part because MedQuest's contrast procedures were directly supervised by physicians, even though the supervising physicians had not been pre-approved by the carrier, the 6th Circuit held that MedQuest provided the level of supervision required under this reasonable and necessary standard and thus did not violate the condition of payment.

The 6th Circuit followed the majority of other circuits and reaffirmed its view that "'[t]he False Claims Act [(FCA)] is not a vehicle to police technical compliance with complex federal regulations' when it determined that statements and requirements in a . . . provider's Medicare application did not permit suit under the FCA."

The 6th Circuit noted that although the FCA retains an important role in the Medicare context, "where, as in this case, the violations would not 'natural[ly] tend[]' to influence' CMS's decision to pay on the claims, . . . the 'blunt[ness]' of the FCA's hefty fines and penalties makes them an inappropriate tool for ensuring compliance with technical and local program requirements like the special supervision requirements at issue in this case."

The 6th Circuit further ruled that MedQuest's failure to update its enrollment information was not a violation of a condition of payment. Specifically, the 6th Circuit ruled that "[I]n the absence of a regulation conditioning payment on an accurate, updated enrollment form reflecting current ownership, and without support for the proposition that a purchaser of a corporate practice is not legally entitled to use that corporation's billing number, MedQuest cannot be held liable under the FCA."

The 6th Circuit concluded that "the FCA does not impose liability for providers' failure to anticipate needs of the [Medicare] program that have not been promulgated in regulations conditioning payment on compliance, in addition to providers' obligations to navigate the already-complicated scheme of regulations."

**Importance of this Decision**

- The importance of this decision, as others like it, is that it draws a distinction between conditions of participation or enrollment and conditions of payment in the application of the federal False Claims Act – something which cannot be understated.
- Many (if not all) providers and suppliers from time to time discover instances where they determine they are not in compliance with a condition of participation, a condition for coverage, or an enrollment requirement, and must determine what the appropriate remedy is to such an issue, which would include a variety of possible actions, including, but not
limited to refunding prior payments, correcting the enrollment issue by filing an updated Medicare enrollment form, etc. At that point whether such a failure rises to the level of a false claim or not is a material consideration as it will color what options are open to the provider or supplier attempting to remedy the issue.

- For a complete copy of the legal alert and additional information on this case, see: http://www.healthlawyers.org/Members/PracticeGroups/HLL/alerts/Pages/SixthCircuitRulesPhysicianSupervisionRulesPertainingtoIDTFsarenotConditionsofPaymentandReversetheDistrictCourt'sJudgment.aspx#sthash.YjDIDvAe.dpuf

3. **Tolling Doctrine Inapplicable to Medicare PRRB Appeals**

   *Sebelius v. Auburn Regional Medical Ctr.*, 133 S. Ct. 817, 184 L. Ed. 2d 627 (2013)

- This case involved the federal government's appeal of a June 2011 ruling by the D.C. Circuit Court that a group of eighteen hospitals was entitled to toll the 180-day deadline for filing an appeal with the PRRB in order to contest unfavorable MAC decisions regarding DSH payments up to 10 years earlier, based on a claim that the CMS's miscalculation of the hospital's DSH payments went undiscovered for that period of time.
- The D.C. Circuit Court ruling reversed the U.S. District Court for the District of Columbia, which earlier held that the plaintiffs had "proffered nothing suggesting that Congress intended to authorize equitable tolling for provider claims."
- In a unanimous decision, the U.S. Supreme Court reversed the U.S. Court of Appeals for the District of Columbia Circuit and agreed with the government, holding that the presumption in favor of equitable tolling does not apply to the 180-day deadline for healthcare providers to file administrative appeals with the Provider Reimbursement Review Board (PRRB).
- More specifically, Justice Ginsburg delivered the opinion of the Court, holding:
  - The statutory limitation on PRRB appeals, as set forth in 42 U.S.C. Section 1395oo(a)(3), is not jurisdictional;
  - The HHS Secretary reasonably construed the statute to permit a regulation extending the time for a provider's appeal to the PRRB to three years; and
  - The presumption in favor of allowing equitable tolling does not apply to administrative appeals of the kind at issue in this case.
- In the briefing, the government argued that allowing equitable tolling in such instances would put a significant financial and administrative burden on the U.S. Department of Health & Human Services (HHS) as it processes reimbursement claims.

*Importance of this Decision*

- While the Court did not rule out application of the doctrine, it indicated that equitable tolling principles are inapplicable to internal administrative deadlines in most contexts—a conclusion that drew a lone protest from Justice Sonia Sotomayor, who suggested in

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10 Special thanks to Kim T. Le, Esquire (Nelson Mullins Riley & Scarborough LLP, Washington, DC), for authoring the original RAP Legal Alert, "U.S. Supreme Court Finds Tolling Doctrine Inapplicable to Medicare PRRB Appeals" on which this section of the outline was based.
concurrence that the Court would face a different case if the private party involved were 
not a "sophisticated" entity capable of looking after its own interests, or if the Secretary 
defined "good cause" so narrowly "as to exclude cases of fraudulent concealment and 
eQUITABLE estoppel."

- For a complete copy of the legal alert and additional information on this case, see: 
  http://www.healthlawyers.org/Members/PracticeGroups/RA/emails/alerts/Pages/USSupreme 
  CourtFindsTollingDoctrineInapplicabletoMedicarePRBAppeals.aspx#sthash.NFymy 
  ibu.dpuf