

HEALTH LAW

Update

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

The Proposed 2010 Medicare Physician Fee Schedule: Imaging Takes Another Hit; and Electronic Health Records Are Everybody's New Best Friend

July 16, 2009

On July 13, 2009, the Centers for Medicare & Medicaid Services ("CMS") published the proposed 2010 Medicare Physician Fee Schedule (the "2010 MPFS Proposed Rule") in the Federal Register.¹ In addition to payment updates, the 2010 MPFS Proposed Rule includes provisions relating to the federal physician self-referral statute (commonly referred to as the "Stark Law"), durable medical equipment, physician quality reporting initiatives, and e-prescribing incentive programs. This *Health Law Update* briefly summarizes some of these proposed changes.

Imaging Payments Cut Again

Perceived overutilization and abuse have made advanced diagnostic imaging services (e.g., CT, MRI and PET) an area of focus for CMS in recent years. Reimbursement rates for these services have been cut repeatedly and the 2010 MPFS Proposed Rule includes a provision that would continue this trend. In a highly technical amendment, CMS proposes to raise the equipment utilization rate (a major assumption that is the basis for the calculation of the reimbursement rates for the technical component of advanced diagnostic imaging services) from the current rate of 50% to a new rate of 90% for equipment priced over \$1 million.² Industry experts predict that such a change would reduce reimbursement for the technical component of advanced diagnostic imaging services by as much as 40% for 2010.

The methodology for calculating reimbursement for the technical component of advanced diagnostic imaging services has historically assumed an equipment utilization rate of 50%. In earlier rulemakings, CMS noted that if the assumed utilization rate was too high, the result would be an insufficient allowance at the service level for the practice costs associated with the equipment; and if the assumed equipment usage percentage was set too low, the result would be

¹The 2010 MPFS Proposed Rule is currently available online at <http://edocket.access.gpo.gov/2009/pdf/E9-15835.pdf>.

² 74 Fed. Reg. 3351-33.

an excessive allowance for the practice costs of equipment at the service level. CMS previously acknowledged that the current assumption of 50% does not capture the actual usage rates for all equipment, but the agency did not believe that it had strong empirical evidence to justify any alternative approaches. In March 2009, the Medicare Payment Advisory Commission (MedPAC) published new data about advanced diagnostic equipment utilization in its Report to Congress.³ CMS believes this new data demonstrates that the current assumption is too low and supports a reduction in reimbursement for advanced diagnostic imaging services. The agency will continue to explore data related to usage rates of equipment priced at less than \$1 million.

Sustainable Growth Rate Modification Regarding Payment for Physician-Administered Drugs

CMS has used the sustainable growth rate (SGR) system to update Medicare Physician Fee Schedule (the "MPFS") rates since 1999. The intended purpose of the SGR system is to limit growth in expenditures for physicians' services. In a given year, if expenditures exceed a specified percentage amount (determined by statute), the MPFS update is reduced the following year. Because the SGR is a cumulative system, past increases in spending levels above the target continue to affect subsequent years until sufficient adjustments have been made to bring actual spending down to the target level.

In each of the past several years, Congress has passed legislation to avert reductions to the MPFS that would otherwise have been required under the SGR. As a result, CMS estimates that actual spending from the 1996/97 base year through December 2009 exceeds the cumulative target by \$69.7 billion. Historically, the costs of physician-administered drugs, which are not paid under the MPFS, have been included in CMS' calculations of actual and target expenditures under the SGR. However, CMS asserts that "growth in the cost of prescription drugs has far outpaced growth in the cost of other physicians' services."⁴ Therefore, according to CMS, "since the inception of the SGR methodology, prescription drugs have accounted for an increasingly disproportionate amount of the growth in spending on physicians' services."⁵

In the 2010 MPFS Proposed Rule, "in anticipation of enactment of legislation to provide fundamental reforms to Medicare physician payments," CMS proposes to remove physician-administered drugs from the calculations of actual and target expenditures under the SGR. As proposed, this rule would apply both retrospectively for each year back to the 1996/97 base year and prospectively to future SGR calculations. CMS notes that, although this proposal to remove physician-administered drugs from the SGR calculations would reduce the past discrepancy between actual and target expenditures, it would not change the projected 21.5% physician payment rate reduction for services furnished on or after January 1, 2010. However, the proposal would reduce the number of years in which physicians are projected to experience a negative update going forward.

³ See Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (March 2009), available at http://www.medpac.gov/documents/Mar09_EntireReport.pdf. In the proposed rule, CMS states that the MedPAC data confirms that imaging facilities would never invest in advanced diagnostic imaging equipment if the equipment were only intended to be used half of the time. The agency believes that the new assumption will more accurately reflect actual rates of utilization.

⁴74 Fed. Reg. 33650.

⁵*Id.*

Physician Quality Reporting Initiative

The Physician Quality Reporting Initiative ("PQRI") is a voluntary reporting program, first implemented in 2007, that provides an incentive payment to eligible professionals (EPs) who satisfactorily report data on quality measures for covered professional services furnished to Medicare beneficiaries during a specified reporting period.⁶ Under the proposed rule, CMS proposes to retain the two reporting mechanisms available to submit data on PQRI quality measures – claims-based reporting and registry-based⁷ reporting. Further, for registry-based reporting, CMS has proposed that EPs enter into an appropriate legal arrangement with a qualified 2010 PQRI registry, in which the registry would act as a HIPAA Business Associate and agent of the EP.

In addition, to promote the adoption and use of electronic health records ("EHR"), CMS has proposed adding an EHR-based reporting mechanism to provide both EPs and CMS with experience on EHR-based quality reporting.⁸ Under the proposed rule, CMS would begin accepting data from qualified EHR products on ten proposed individual PQRI measures. In addition, CMS would permit EPs to count their submission of EHR-based measures towards their eligibility for a PQRI incentive payment. For 2010, CMS proposes that EPs who satisfactorily report data on at least three of the ten proposed EHR-based individual PQRI measures be eligible for an incentive payment.⁹ In years past, EHR-based measure submission has been on a voluntary or "pilot" basis and has not counted towards an EP's eligibility for incentive payment. CMS has decided not to propose making the EHR-based reporting mechanism available for measures groups (as opposed to individual measures). CMS is also considering significantly limiting the claim-based mechanism for reporting data after 2010 in order to allow EPs to devote more resources to maximizing the potential of registries and EHRs.¹⁰

There are a number of proposed reporting options and reporting periods available for 2010. Under the proposed rule, CMS has proposed that 2010 PQRI reporting data for individual PQRI quality measures through claims or qualified EHR will be the entire year (January 1, 2010 through December 31, 2010). CMS has also proposed that data reported through registries or through reporting measures groups would be either for the entire year (January 1, 2010 through

⁶74 Fed. Reg. 33559. "Eligible professionals" include physicians (*i.e.*, M.D., D.O., D.P.M., O.D., D.D.S. (oral surgery), D.D.M., and D.C.), non-physician practitioners (*i.e.*, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists (and anesthesiologist assistants), certified nurse midwives, clinical social workers, clinical psychologists, registered dietitians, nutrition professionals and audiologists), physical therapists, occupational therapists and qualified speech-language therapists. "Eligible Professionals": *See* CMS, "Physician Quality Reporting Initiative, Eligible Professionals," available at http://www.cms.hhs.gov/pqri/10_eligibleprofessionals.asp. For 2010, EPs may earn an incentive payment of 2.0% of the EP's estimated total allowed charges (based on claims submitted not later than 2 months after the end of the reporting period) for all covered professional services (*i.e.*, services furnished by an EP for which payment is made under, or is based on, the MPFS) furnished during the reporting period for 2010. *See* 74 Fed. Reg. 33559.

⁷Registry-based reporting entails EPs submitting PQRI quality measures to a qualified PQRI registry and requesting that the registry submit PQRI quality measures results on their behalf. *See* 74 Fed. Reg. 33559-560. CMS will post a list of qualified registries on their website in 2010 after posting the final PQRI registry requirements, which are also described in the proposed rule. *See* 74 Fed. Reg. 33560-562.

⁸Data submission for the 2010 PQRI from the EHR-based reporting mechanism would need to be completed by March 31, 2011. The rule also describes the requirements and process to become a qualified EHR vendor. *See* 74 Fed. Reg. 33563-33565.

⁹74 Fed. Reg. 33563.

¹⁰CMS believes that registry and EHR-based reporting allow for more sophisticated and timely reporting on clinical data measures. *See* 74 Fed. Reg. 33561.

December 31, 2010) or through a 6-month reporting period beginning on July 1, 2010 through December 31, 2010.¹¹

Additional changes in the proposed rule would include implementing provisions of the MIPPA that would enable group practices¹² to qualify for an incentive payment based on a determination at the group practice level, rather than at the individual EP level, that the group practice (on a unique reporting mechanism) has satisfactorily reported data on PQRI quality measures. Previously, there were no incentive payments made to the group practice based on a determination that the group practice, as a whole, satisfactorily reported the PQRI quality measures data. Thus, payment may now be made to a qualified group practice as a whole and individual physicians participating in a group practice reporting option can no longer separately earn a PQRI incentive payment as an individual.¹³

CMS has also proposed changes to the criteria for satisfactorily reporting quality measures.¹⁴ As proposed, changes would include the number and frequency of individual quality measures on which an EP would be required to report, as well as including a minimum patient sample size for reporting quality measures to be fifteen (15) Medicare Part B FFS patients for the 12-month reporting period for both individual reporting and reporting measures groups and thirty (30) patients for the 6-month reporting period available for measures groups. Overall, CMS has anticipated adding twenty-two (22) individual PQRI measures and six (6) measures groups on which individual eligible professionals may report, as well as retiring seven (7) individual PQRI measures.¹⁵

E-Prescribing Incentive Program

In 2009, CMS established a five-year program of incentive payments to EPs who are "successful electronic prescribers" ("E-prescribers") through an E-Prescribing Incentive Program ("Program"). Beginning in 2012, the Program will also impose penalties on EPs who are not successful e-prescribers. CMS expects this combination of financial incentives and payment will encourage significant expansion of the use of e-prescribing. "Successful E-Prescribers" will be eligible to earn an incentive payment equal to 2.0%¹⁶ of the total estimated allowed charges for all covered professional services during the 2010 reporting period. EPs would be eligible for the E-prescribing incentive payment regardless of whether they participate in the PQRI program. However, if participating in the PQRI program, EPs would be able to receive e-prescribing incentive payments in addition to any incentive payments that they may earn through the PQRI program.¹⁷ In addition, if the EP earns an EHR incentive payment under the HITECH provisions of the American Recovery and Reinvestment Act of 2009, he or she would not be

¹¹For the 6-month reporting period, incentive payments would only apply to the 6 month reporting period and not the entire year. *See* 74 Fed. Reg. 33560.

¹²"Group Practice" is proposed by CMS to be defined as 200 or more individual professionals who reassigned their billing rights to the TIN, but is considering lowering the group size threshold in the future. *See* 74 Fed. Reg. 33570.

¹³74 Fed. Reg. 33559.

¹⁴Satisfactory quality measures can differ depending on the reporting period, whether submitted by a group or individual, and the type of reporting mechanism an EP chooses to use. *See* 74 Fed. Reg. 33565-571.

¹⁵*See* 74 Fed. Reg. 33574-587.

¹⁶For 2011 and 2012, the incentive payment would be reduced to 1.0% and then reduced further to 0.5% in 2013. *See* 74 Fed. Reg. 33594-595.

¹⁷*See* 74 Fed. Reg. 33594.

eligible for a separate incentive payment under the E-Prescribing Program. EPs who are not successful prescribers by 2012 would see a downward adjustment in their fee schedule by 1.0% for the 2012 reporting year, a 1.5% reduction in 2013, and a 2.0% reduction in 2014.

In addition, for Calendar Year 2010, CMS has proposed to simplify the reporting requirements for the electronic prescribing measure by streamlining how often an EP has to report e-prescribing information to CMS. For 2010, CMS proposes that EPs report an e-prescribing code only when a patient visit results in an electronic prescription. CMS proposes that EPs will need to report this code at least 25 times during the reporting period to be considered a successful electronic prescriber.¹⁸ By contrast, CMS required EPs in 2009 to report one of several e-prescribing codes, based on different scenarios that characterized the presence or absence of an electronic prescription during a patient visit, and those codes were to be reported at least 50% of the time.

For 2010, in addition to the current claims-based reporting mechanism, CMS has proposed that EPs would be allowed to report the e-prescribing measure through qualified registries or through a qualified EHR product. These registries and EHR products must qualify for the 2010 PQRI to be eligible to submit quality measure results. CMS has also proposed to broaden eligibility for the e-prescribing incentive by including professional services furnished in skilled nursing facilities or the home care setting as part of the list of services for which the electronic prescribing measure is reportable. Further, CMS plans to implement a MIPPA provision that enables group practices to qualify for a 2010 e-prescribing incentive payment based on a determination at the group practice level that the group practice is a successful electronic prescriber, rather than at the individual eligible professional level. However, unlike individual EPs, group practices must participate in the 2010 PQRI program to be eligible for incentive payments under the e-prescribing program and must report at least one prescription during an encounter generated in at least 2,500 instances during the reporting period.¹⁹

Other Proposed Changes

- *DMEPOS Competitive Bidding Program.* In 2007, CMS established a Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) competitive bidding program in an effort to reduce beneficiary out-of-pocket expenses and Medicare costs for durable medical equipment. Under the program, suppliers would compete for the right to provide durable medical equipment to all Medicare beneficiaries in a particular geographic area (referred to as a "competitive bidding area") and CMS would award an exclusive contract to the supplier that offered the best price and met applicable quality and financial stability standards. The first round of DMEPOS competitive bidding ("Round 1") was completed in early 2008, but MIPPA retroactively terminated all of the contracts that were awarded to suppliers in Round 1 and prohibited CMS from making any payments to suppliers based on such contracts. MIPPA also required CMS to establish a procedure by which suppliers who suffered damages because their contracts

¹⁸However, to qualify as a "successful e-prescriber," CMS has also proposed that an EP meet a 10% threshold of the total Part B allowed charges for all covered professional services for which e-prescribing quality measures apply. See 74 Fed. Reg. 33598.

¹⁹Each individual in a group practice must also report at least 1 electronically prescribed prescription 25 times during a reporting period. In addition, the 10% threshold of e-prescriptions for applicable Part B allowed charges would also apply for the group practice. See 74 Fed. Reg. 33598.

were terminated could be compensated. CMS outlines these proposed procedures in the 2010 MPFS Proposed Rule.

Under the proposal, any supplier that was awarded a contract in Round 1 and believes that it has suffered damages as a result of the termination of that contract is eligible to submit a claim. In order to receive compensation, the amount of the damages must be substantiated and the damages must be a direct result of the termination of the Round 1 contract. In addition, the supplier must be able to demonstrate exactly how it was damaged and must provide detail about any steps taken by the supplier to mitigate any potential damages. Every effort will be made to make a final determination within 120 days of initial receipt of the claim for damages. In the case of more complex cases, or in the event of a large workload, a decision will be issued as soon as practicable.

- *Changes to Compensation for Anesthesia Teaching Programs.* The regulations do not presently address whether medical direction special payment rules²⁰ for teaching anesthesiologists ("TAs") apply to cases involving a single resident that is concurrent to another case involving a CRNA, AA, other qualified individual who can be medically directed. CMS proposes to add language that the special payment rule for TAs applies to resident cases where the TA is involved in two concurrent resident cases or in one resident case that is concurrent to another case paid under medical direction special payment rules.²¹
- *Accreditation Standards for Suppliers of Advanced Diagnostic Imaging Services.* In order to address concerns about rapid growth in high cost imaging services²², CMS is proposing to implement a requirement in Section 135 of the MIPPA that suppliers of the technical component ("TC") of advanced imaging diagnostic services²³ ("Suppliers") be accredited beginning January 1, 2012, for payments made under the PFS. CMS would designate and approve accrediting organizations (AOs) for these suppliers and would utilize the imaging quality standards that have been developed by the AOs. Specifically, the AOs would apply standards that set qualifications for medical personnel who are not physicians but who furnish the TC and would describe the qualifications and responsibilities of medical directors and supervising physicians. In addition, the AOs would apply standards to mobile units, physicians' offices, and independent diagnostic testing facilities that create the images, but would not apply to the physician who interprets them. The standards would require Suppliers to: (1) establish and maintain a quality control program to ensure technical quality; (2) ensure the equipment meets performance specifications; (3) ensure the safety of personnel; and (4) any other standard

²⁰When furnishing medical direction in up to four multiple concurrent procedures, the special payment rules allow an anesthesiologist to be paid for 50% of the otherwise applicable physician fee schedule for each procedure. See Fed. Reg. 33603.

²¹*Id.*

²²According to the GAO, spending on advanced imaging services is growing almost twice as fast as spending on other types of imaging services, and is a significant contributor to the rapid growth in health care spending in recent years, but there is little administrative oversight to ensure the quality of care. See <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=3469&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date>.

²³"Advanced Diagnostic Imaging Centers" in this section is proposed to be defined to include only magnetic resonance imaging, computed tomography, nuclear medicine, and positron emission tomography. See Fed. Reg. 33652.

the Secretary deems appropriate. CMS also proposes to conduct audits of both Suppliers and AOs for disparities between the AO and CMS' independent findings.²⁴

- *New Benefits for Cardiac Rehabilitation, Pulmonary Rehabilitation and Chronic Kidney Disease.* The proposed rule would also implement provisions in the MIPPA that added new Medicare benefit categories for intensive cardiac and pulmonary rehabilitation services and for chronic kidney disease (CKD) education, beginning January 1, 2010. The proposed rule outlines what these programs would entail, how they would be paid under the MPFS, and the criteria for covering these services. For both intensive cardiac and pulmonary rehabilitation,²⁵ CMS has proposed to create new conditions for coverage and two new HCPCS codes under Medicare Part B for payment for CMS-approved programs,²⁶ beginning on January 1, 2010.²⁷ Coverage for these two programs will generally be based on the implementation of a physician supervised program for individual patients that includes physician prescribed aerobic exercise, evaluation, training, education and outcomes assessment. Covered settings include only a physician's office or hospital on an outpatient basis where a physician must be immediately available for medical consultation and emergencies.

CMS also has proposed to create a new Medicare Part B covered benefit for kidney disease patient education for patients with Stage IV Chronic Kidney Disease effective for services furnished on or after January 1, 2010. Education must include face-to-face educational services by a physician, physician assistant, or nurse practitioner, or certain rural service providers, in which a patient is provided with comprehensive information regarding kidney disease, therapeutic and treatment options, test results, management of co-morbidities, and assessment of outcomes. Further, patients must have the opportunity to actively participate in his or her choice of therapy.²⁸

Clarification of Stark "Stand in the Shoes" Commentary

The 2010 MPFS Proposed Rule seeks to clarify one aspect of Stark's physician stand in the shoes provision. Phase III of the Stark regulations, issued in 2007, as amended by the 2009 final inpatient prospective payment system (IPPS) rule, added a provision under which all physician owners (other than titular owners) of a group practice are treated as "standing in the shoes" of their physician organizations for purposes of applying the rules that define direct and indirect compensation arrangements in 42 C.F.R. § 411.352.²⁹ Under the stand in the shoes provision, a physician owner who stands in the shoes of his or her physician organization would be considered to have the same compensation arrangements (with the same parties and on the same

²⁴*Id.*

²⁵See Fed. Reg. 33651-652.

²⁶Intensive Cardiac Rehabilitation is also commonly referred to as a lifestyle modification program, furnished in a highly structured environment which may be more lengthy and rigorous than regular cardiac rehabilitation. See Fed. Reg. 33651-652.

²⁷See Fed. Reg. 33651-652.

²⁸See Fed. Reg. 33651.

²⁹For a more detailed description of the stand in the shoes provision, as well as other changes implemented in Phase III of the Stark regulations, please see our *Health Law Updates* entitled "Stark Phase III Regulations, First of Two-Part Series: 'What Meets the Eye,'" dated September 14, 2007 and "Stark Phase III Regulations, Second of Two-Part Series: 'More than Meets the Eye,'" dated October 12, 2007, each available at www.bassberry.com.

terms) as the physician organization in whose shoes the referring physician stands. CMS has stated that:

[f]or purposes of applying the exceptions in § 411.355 and § 411.357 to arrangements in which a physician stands in the shoes of his or her physician organization, the 'parties' to the arrangements are considered to be the entity furnishing DHS and the physician organization (including all members, employees, or independent contractor physicians).³⁰

Since the promulgation of the stand in the shoes rule, CMS has been grappling with several ambiguities and misinterpretations arising from the language. First, the language apparently led many to believe that everyone within a physician organization (*i.e.*, all members, employees, and independent contractor physicians) must be signatories to all of the various arrangements between the physician organization and each DHS entity.³¹ CMS rectified the misinterpretation in January 2008 by posting an FAQ on the CMS website.³²

Second, according to CMS, some members of the industry erroneously applied the stand in the shoes provision by analyzing only whether the compensation takes into account the referrals between the entity furnishing DHS and the physician who stands in the shoes of the physician organization, not the referrals of all members, employees, and independent contractor physicians in the physician organization.³³ In the 2010 MPFS Proposed Rule, CMS proposes to modify the second sentence of 42 C.F.R. § 411.354(c)(3)(i) to correct this misinterpretation and to further clarify the agency's position. The proposed language would provide that:

[w]hen applying the exceptions in § 411.355 and § 411.357 to arrangements in which a physician stands in the shoes of his or her physician organization, the relevant referrals and other business generated 'between the parties' are referrals and other business generated between the entity furnishing DHS and the physician organization (including all members, employees, and independent contractor physicians).³⁴

CMS has requested that any comments to the proposals in the 2010 MPFS Proposed Rule be received by 5:00 pm on August 31, 2009. If you have any questions about any of the topics in this *Health Law Update*, please contact one of the attorneys in our Healthcare Practice Group listed below.

Bass, Berry & Sims Healthcare Attorneys

³⁰ 74 Fed. Reg. 33644.

³¹ *Id.*

³² See CMS FAQ #8885, available at http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_adp.php?p_faqid=8885. In this FAQ, CMS states that physicians standing in the shoes of their physician organization do not need to sign agreements between the physician organization and the DHS entity because CMS considers such a physician to have signed the agreement when the physician organization's authorized signatory signs the agreement.

³³ 74 Fed. Reg. 33644.

³⁴ *Id.*

H. Stanford Adams, Jr.
(615) 742-7775
sadams@bassberry.com

H. Lee Barfield, II
(615) 742-6202
lbarfield@bassberry.com

Philip F. Berg
(615) 742-7908
pberg@bassberry.com

Krista Thornton Cooper
(615) 742-7734
kthornton@bassberry.com

Mary Beth Fortugno
(615) 742-7739
mfortugno@bassberry.com

Pooneh Ghiassi
(615) 742-7782
pghiassi@bassberry.com

Anna Grizzle
(615) 742-7732
agrizzle@bassberry.com

Elisa E. Harris
(615) 742-6553
eharris@bassberry.com

Angela Humphreys
(615) 742-7852
ahumphreys@bassberry.com

Clevonne M. Jacobs
(615) 742-7769
vjacobs@bassberry.com

J. James Jenkins, Jr.
(615) 742-6236
jjenkins@bassberry.com

Seth A. Killingbeck
(615) 742-7707
skillingbeck@bassberry.com

David King
(615) 742-7890
dking@bassberry.com

Claire F. Miley
(615) 742-7847
cmiley@bassberry.com

T. Scott Noonan, Co-Chair
(615) 742-6273
snoonan@bassberry.com

Brenda N. Phillips
(615) 742-6237
bnphillips@bassberry.com

Shannon Pinkston
(615) 742-7727
spinkston@bassberry.com

Cynthia Y. Reisz
(615) 742-6283
creisz@bassberry.com

Brian D. Roark
(615) 742-7753
broark@bassberry.com

Scott B. Shanker
(901) 543-5932
sshanker@bassberry.com

Catherine J.B. Sloan
(615) 742-7789
csloan@bassberry.com

Danielle M. Sloane
(615) 742-7763
dsloane@bassberry.com

Nesrin Garan Tift
(615) 742-7903
ntift@bassberry.com

Leigh Walton, Co-Chair
(615) 742-6201
lwalton@bassberry.com

Elizabeth S. Warren
(615) 742-7719
ewarren@bassberry.com

Douglas M. Wolford
(615) 742-7917
dwolford@bassberry.com

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315 Deaderick Street • Suite 2700 • Nashville, TN 37238-3001 • (615) 742-6200
The Tower at Peabody Place • 100 Peabody Place, Suite 900 • Memphis, TN 38103-3672 • (901) 543-5900
1700 Riverview Tower • 900 S. Gay Street • Knoxville, TN 37902 • (865) 521-6200