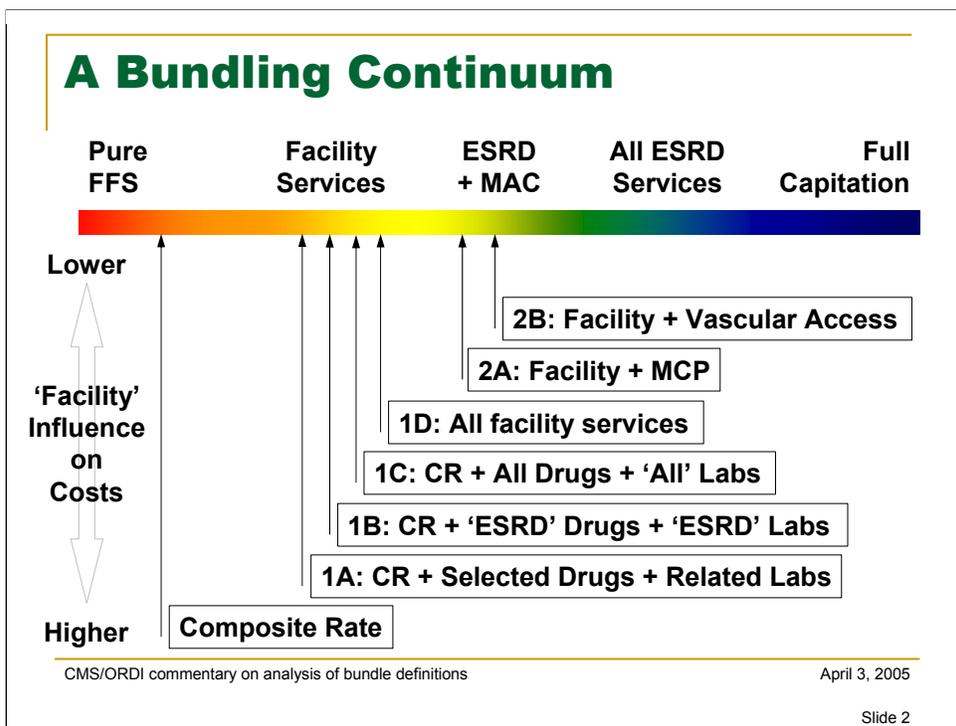


ESRD Bundled Payment Demonstration (MMA §623e)

CMS/ORDI Commentary
On analysis of initial bundle definitions

April 13, 2005

- This document discusses the data on various bundling options. It is intended to provide a starting point for discussion but also for more detailed review of the extensive data tables that accompany this report.
- It has a number of specific goals:
 - It outlines the general framework for defining bundles—what has been referred to as a 'bundling continuum'.
 - It reviews a few key characteristics of the data that are available to provide descriptive data on the components of different bundles.
 - It reviews the definition of what is and is not included in each bundle.
 - It provides a summary discussion of the patterns that are apparent in the accompanying data tables. As such it also serves as a kind of guide to reading those tables.
 - It's most important goal is to distill from the data some key implications of the data that, it is hoped, can serve as a starting point for further discussion.



- The services that might be included in a bundle may be placed along a continuum, although this inevitably involves some arbitrary decisions. However, the general notion is to place services along the continuum based on proximity to the care that is initiated, directed, coordinated or influenced by the dialysis facility.
- Each bundle defines the services that the dialysis facility is responsible for providing directly or providing through arrangements with other providers.
- In general, several distinctive bundles can be identified. Four of these involve 'facility' services. Two substantially expand the bundle to include certain physician payments and certain payments related to vascular access.
 - Four bundles involve services that the facility directly participates in providing:
 - Bundle 1A would include composite rate services, selected drugs provided by the facility, and selected lab tests
 - Bundle 1B adds to 1A the remaining 'major' or 'ESRD' drugs and related lab tests.
 - Bundle 1C adds to 1B all lab tests generally ordered for ESRD patients.
 - Bundle 1D adds to 1C all remaining services currently billed by dialysis facilities. In effect 1D represents an option of making all payments to the facility through the bundled payment rate.
 - Bundle 2A would add to the facility payment the MCP payment.
 - Bundle 2B would add to the facility payment non-professional payments for vascular access (and related) procedures.

The Narrow Bundles

- Composite Rate services / payment
- Injectable drug options
 - Option 1A: EPO, Iron, Vitamin D
 - Option 1B: 'Major' drugs
 - Option 1C: 'All' drugs (billed by facility)
- Laboratory test options
 - Option 1A: Tests related to EPO, Iron, Vitamin D
 - Option 1B: Tests related to 'major' drugs
 - Option 1C: 'All' laboratory tests
- Other separately billable services
 - Option 1D: All SB services other than drugs / lab tests

CMS/ORDI commentary on analysis of bundle definitions

April 3, 2005

Slide 3

- Composite rate services are included in all options.
- Options A through C vary in terms of the drugs and laboratory tests included:
 - Option A includes three classes of drugs (EPO, Iron, and Vitamin D) and laboratory tests related to those three classes of drugs.
 - Option B includes the 11 categories of 'ESRD' drugs (which include the option A drugs) and laboratory tests related to those 11 categories of drugs. Ideally, the laboratory tests included in this option would be based on clinical judgment, i.e., those tests that are needed to monitor patient need for or response to the specified classes of drugs.
 - Option C includes all drugs and all laboratory tests. The meaning of "all" is a little unclear. It could refer to either: (1) all drugs billed by the dialysis facility, all laboratory tests billed by the facility, and the 'top 50' laboratory tests billed by independent or hospital laboratories for ESRD patients; or (2) all injectable drugs and laboratory tests billed by any provider for ESRD patients. It is probably best to start with the more limited of these definitions, but please advise and explain the rationale.
- Option D would include all services separately billed by dialysis facilities.
- The drugs and laboratory tests included in each bundle are described on pages 3 through 12 of the tables document.

The Basic Questions

- Is this class of drugs or laboratory tests a candidate for inclusion in the bundle?
- Are there specific laboratory tests that:
 - Are included, but should be excluded?
 - Are excluded, but should be included?
- Implications for:
 - Inclusion in bundle
 - Method / mechanism of payment
 - Case mix adjustment
- Note: data do not include tests bundled in CR

CMS/ORDI commentary on analysis of bundle definitions

April 3, 2005

Slide 4

- The most basic question that the following data are intended to facilitate discussion of is whether a particular class of services (i.e., drugs, laboratory tests, etc.) are a good candidate for inclusion in a bundled payment. This basic question is, however, overly simplistic.
- In the case of laboratory tests, the question is whether specific laboratory tests should be included or excluded from the bundle. A preliminary list of laboratory tests served as a starting point for analysis. These tests have been grouped into five categories: tests related to anemia, tests related to vitamin D, tests related to infections, tests related to levocarnitine, and a somewhat inclusive list of 'all lab tests'. The question are whether tests that are included should be dropped, or whether tests that were excluded should be added.
- In discussing the following data the focus of attention keeps returning to the implications of the data for: (a) whether services should be included in the bundle; (b) if included, the method or mechanism of payment; and (c) if included, the impact on the need for or importance of robust case mix or other payment adjustments.
- One thing to keep in mind when reviewing data related to laboratory tests is that the lab data available to CMS include only tests that were billed and paid for. Tests that are already 'bundled' into the composite rate are not included or shown; and, tests that are not paid due to the 50/50 rule are not included or shown.

The Nature of the Data

- Data sources
 - Medicare enrollment files
 - Medicare claims files
 - Social Security Administration files (limited use)
- Characteristics of billing / claims data
 - Billing generates monthly data
 - Per session data calculated from bills
- Aggregation
 - Detailed billing data into categories of service
 - Multiple bills into patient-month records

CMS/ORDI commentary on analysis of bundle definitions

April 3, 2005

Slide 5

- The data used to prepare the tables that accompany this commentary are taken from the standard Medicare claims and enrollment files. The enrollment files provide information on patient characteristics. The claims files provide information on services used and amount of Medicare 'payment' (i.e., Medicare allowable charges/costs). These data may be supplemented for certain analysis with data drawn from Social Security Administration files. However, all data on payments or 'costs' are derived from Medicare claims files.
- Claims or billing data have several characteristics that should be borne in mind. Most providers/suppliers submit claims to Medicare on a monthly cycle. The monthly claim reflects all services provided to the patient and billed to Medicare during that month.
- These data can be expressed on either a 'per month' or 'per session' basis. Per session statistics are calculated from monthly data simply by dividing the number of dialysis sessions billed for the month into the total payments for composite rate services, drugs, laboratory tests, or other services. It is important to note, however, that data on per session payments are not based on a true session-level record. They are simply a transformation of monthly data.
- Additional information on data sources and the methods used to create the data base may be found in the database documentation prepared by KECC.

Caveats on the Data

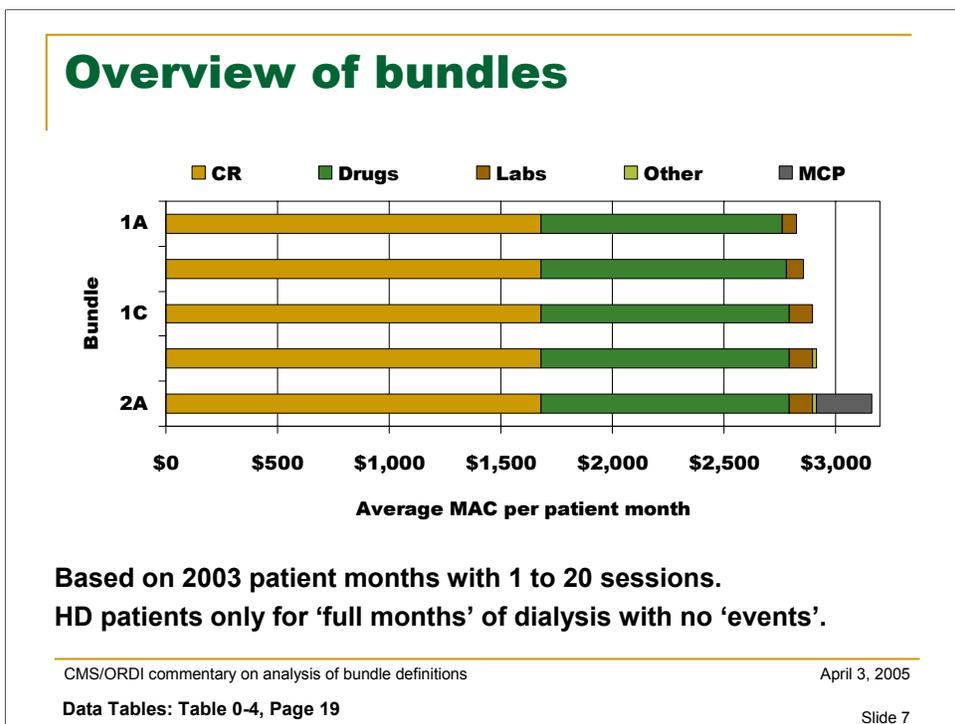
- Represent patterns in 2003
 - Do not reflect new payment policies
 - Do not reflect behavioral response to new policy
 - Do not reflect implementation of Part D
- Implications for distinct uses of data
 - Evaluation of possible bundles
 - Assessment of payment ‘models’
 - Development of case mix adjustment method
 - Calibration of payment model

CMS/ORDI commentary on analysis of bundle definitions

April 3, 2005

Slide 6

- The data that are available for this analysis have several limitations with varying implications for how the data are interpreted.
- The data represent billing and payment patterns in 2003.
 - Payment amounts do not reflect the new payment policies for 2005. These changes will undoubtedly affect absolute dollar amounts. However, they are likely to have a limited impact on patterns across patient characteristics and even (to a more limited degree) facility characteristics.
 - A potentially more serious problem is that the data do not reflect changes in behavior in response to new policies. Until more recent data become available it will be impossible to evaluate rigorously and quantitatively the impact of behavior changes. The interpretation of these 2003 results should be tempered by a critical awareness of the kinds of responses that changes in policy may be causing.
 - A third limitation is related to the potential effect of prescription drug coverage under Part D in 2006. It is even more difficult to precisely anticipate how Part D will affect the patterns shown in the associated tables and charts. However, an important question to keep asking is how these patterns may change—and why—in response to Medicare prescription drug coverage.
- Having noted these limitations, it is also important to recognize that they have different implications for different uses of the data.
 - The historical data are sufficient to support research into possible bundles, payment models and case mix methods, if tested against a critical understanding of how provider behavior is changing,
 - These uses are very different from calibrating the final payment model.



- Before launching into the details of individual bundles, it is useful to establish a general context by examining the 'bottom line' differences across the proposed bundles. The above figure shows average Medicare payments (allowable costs/charges including patient cost-sharing) per patient month (PPM) for hemodialysis patients who received between 1 and 20 dialysis sessions in months during which a 'full month' of dialysis was provided. Months in which 'events' occurred were excluded; these events include hospitalization, transplant, transfer between facilities, change in modality, initiation of dialysis, training, and termination of dialysis because of death or other causes.
- In all bundles, composite rate payments account for \$1,682 PPM (about 58% of total payments for bundles 1A through 1D, 53% for 2A).
- Bundle 1A adds EPO, iron, and 'vitamin D' and related labs. The drug payments add \$1,082 PPM to the total, while the lab payments add \$64 PPM.
- Bundle 1B adds levocarnitine, alteplase, and vancomycin and related labs. Relative to bundle 1A, the three drugs add \$18 PPM, while the related labs add \$11 PPM.
- Bundle 1C adds 7 'injectables' and most lab tests. Relative to bundle 1B, drug payments increase \$11 PPM, while lab payments increase \$32 PPM.
- Bundle 1D adds all other services billed by dialysis facilities. Relative to bundle 1C, payments increase by \$16 PPM.
- Finally, adding the MCP increases payments by \$250 PPM (or about 15% of the composite rate payments)
- The dollar figures used in this figure as presented on the next page.

Incremental Differences

	Average MAC (per patient month) for bundle				
	1A	1B	1C	1D	2A
CR	\$1,682	\$1,682	\$1,682	\$1,682	\$1,682
Drugs	1,082	1,100	1,110	1,110	1,110
Labs	64	75	107	107	107
Other	—	—	—	16	16
MCP	—	—	—	—	250
Total	2,828	2,857	2,900	2,916	3,165

Based on 2003 patient months with 1 to 20 sessions.

HD patients only for ‘full months’ of dialysis with no ‘events’.

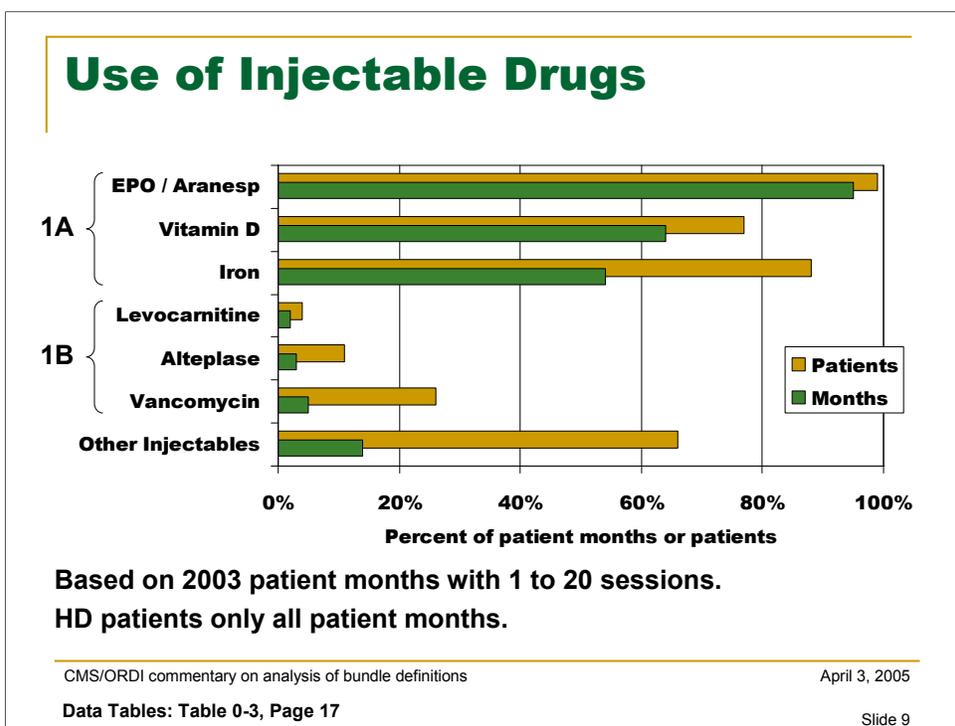
CMS/ORDI commentary on analysis of bundle definitions

April 3, 2005

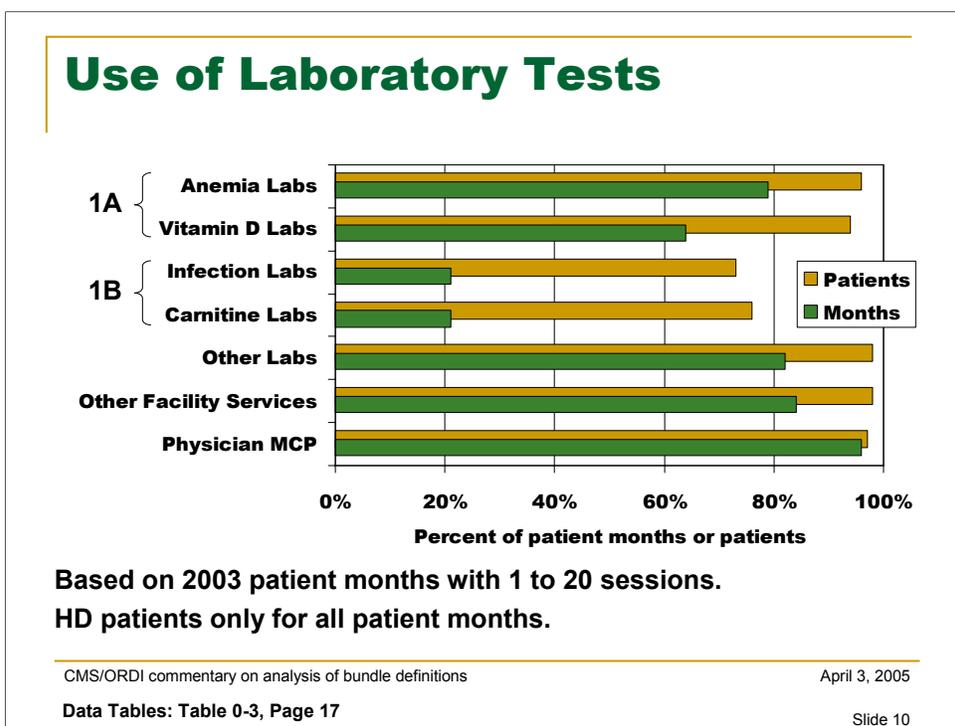
Data Tables: Table 0-4, Page 19

Slide 8

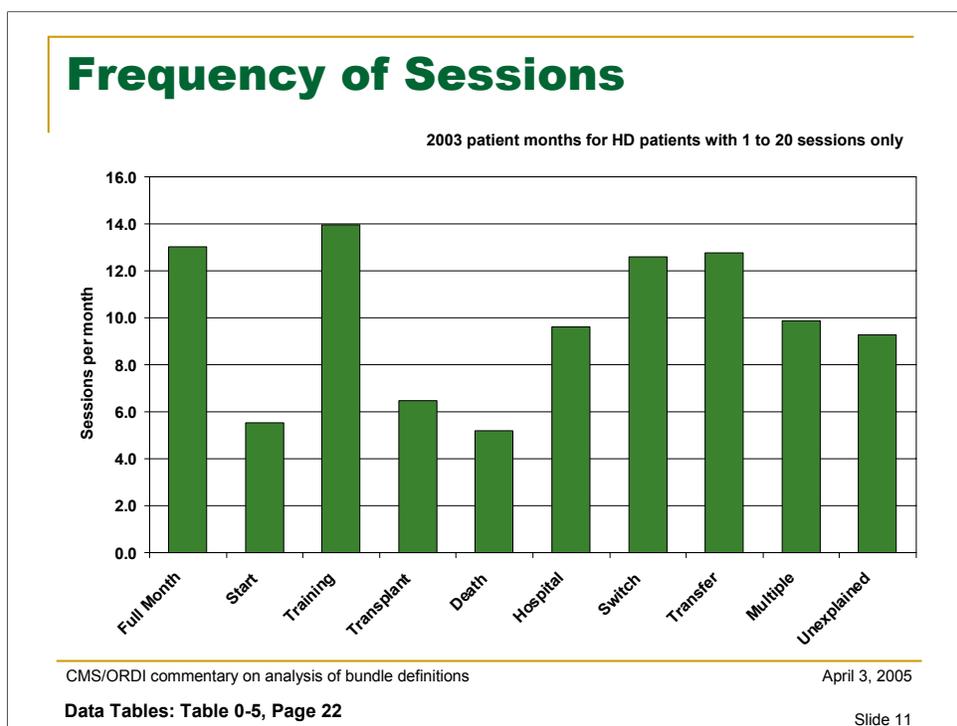
- **In the following discussion the term ‘incremental payments’ refers to services that would be included in the bundle under the most expansive ‘facility services’ option (1D) but that are not included in the composite rate. It therefore differs slightly from the definition of ‘separately billable’ services under the composite rate system.**
- As shown in the previous figure and the above table, nearly all of the increase in payment from bundle 1A through bundle 1D is associated with EPO, iron and ‘vitamin D’. Payments for these drugs represent more than 87% of incremental payments, and more than 97% of all drug payments under the most expansive bundle.
- Laboratory tests that are thought to be ‘related’ to these three classes of drugs are equal to about 4 percent of composite rate payments and just over 5% of incremental payments.
- The addition of levocarnitine, altaplast, and vancomycin (and related laboratory tests) adds less than \$30 PPM to the payment under the bundle (relative to 1A). This represents 2.3% of incremental payments.
- The addition of most remaining injectable drugs and all laboratory tests adds \$43 to the payment under bundle (relative to 1B). This represents 3.5% of incremental payments.
- The addition of all other facility services under bundle 1C adds only \$16 PPM to the bundle. These ‘other facility services’ represent less than 1.5% of total incremental payments.
- **Note that these figures are based on patient months in 2003 for hemodialysis patients only who did not experience any ‘events’ to disrupt a ‘full month’ of dialysis.**



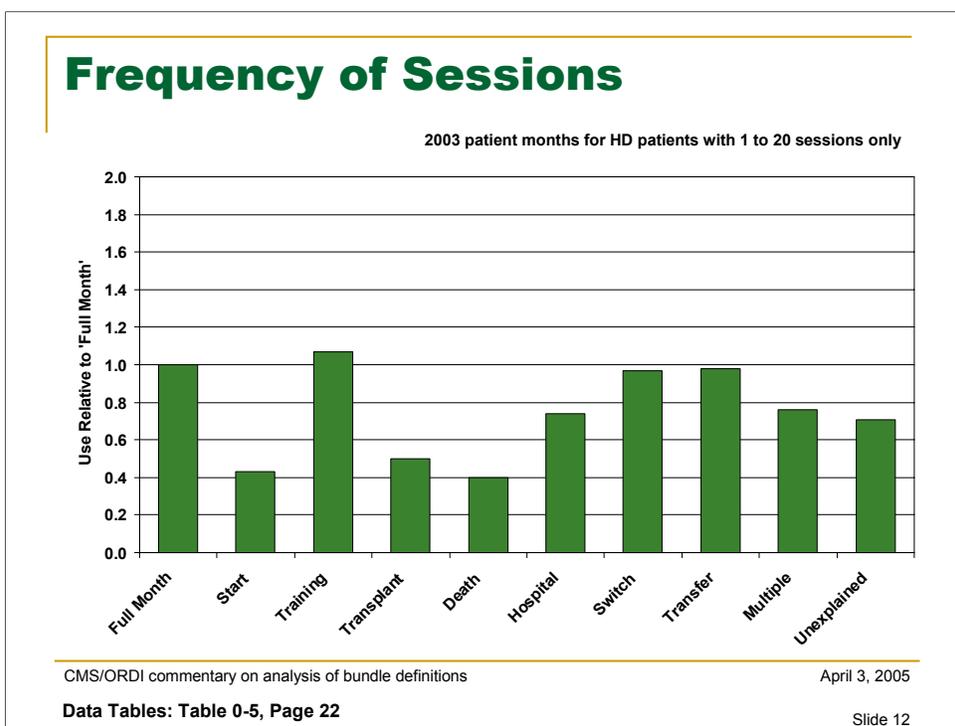
- All patients, by definition, use dialysis services. However, not all patient months involve claims for injectable drugs or laboratory tests. (It should be noted that slightly more than 2% of patient months in the database did not involve claims for any dialysis sessions. The reason for this is, at present, unknown. These 'no dialysis months' were excluded from the analysis.)
- Bundle 1A included the three major classes of drugs used by dialysis patients.
 - Claims for EPO are submitted for nearly all (98%) of hemodialysis patients, and EPO is billed in 95% of patient months.
 - 'Vitamin D' appears to be used less frequently than EPO, at least a form that is covered by Medicare. Claims for 'vitamin D' are submitted for just over ¾ of hemodialysis patients, and 'vitamin D' is billed in 64% of patient months.
 - Claims for iron are submitted for nearly 90% of patients, but iron is billed in just over half (54%) of patient months.
- Use of the drugs included in bundle 1B is much more irregular than use of drugs in bundle 1A. Claims for levocarnitine, alteplase, and vancomycin are submitted for a minority of patients, just 4%, 11%, and 25%, respectively. These drugs are billed in less than 6% of patient months.
- Claims for other injectable drugs are submitted for two-thirds of patients, but are bill in just 14% of patient months. Use therefore appears to be much more irregular than use of EPO, 'vitamin D' and iron, though more common than the drugs included in bundle 1B.
- **Note that these figures are based on patient months in 2003 for hemodialysis patients only. They include all patient months with between 1 and 20 sessions, whether or not any 'events' occurred to disrupt a 'full month' of dialysis.**



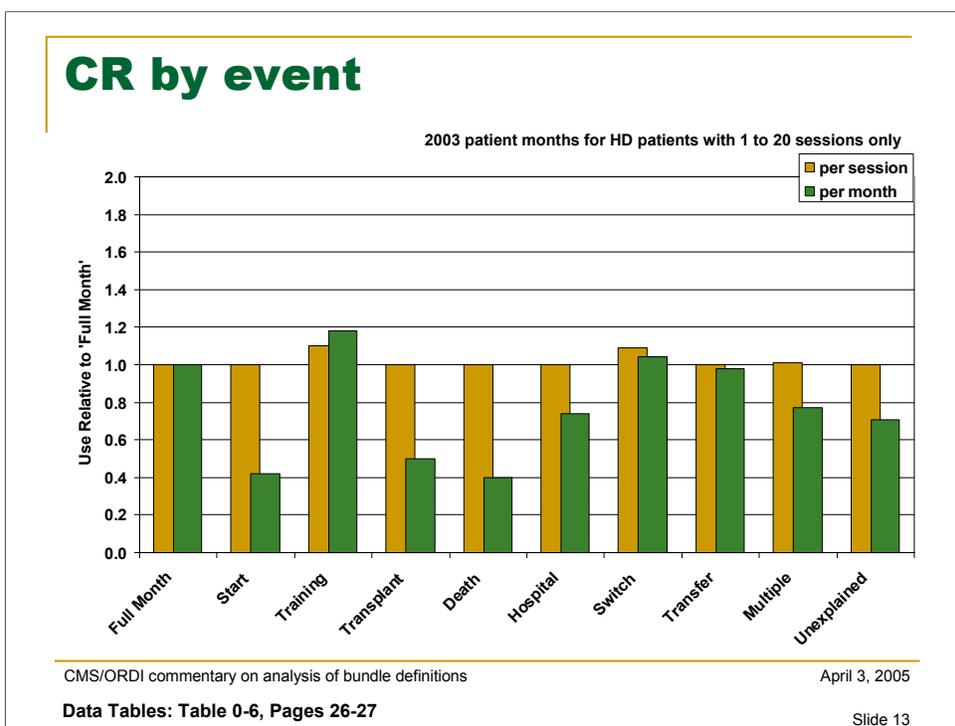
- Laboratory tests that are billed separately and not included in the composite rate are incurred by nearly all patients and are submitted on claims for the vast majority of patient months.
- Claims for the laboratory tests included in bundle 1A, for anemia and management of 'vitamin D', are submitted for more than 95% of patients. Anemia labs are billed in nearly 80 percent of patient months, while 'vitamin D' labs are billed in almost two-thirds of months.
- Claims for the bundle 1B laboratory tests are less common and more irregular, as may be expected. Both 'infection' labs and 'carnitine labs' are submitted for about $\frac{3}{4}$ of dialysis patients, but are billed in only about 20% of patient months.
- As would be expected from the large number and broad purposes of the tests included in bundle 1C, nearly all patients (98%) have claims for these tests, and tests are billed in more than four out of five (80%) of patient months.
- The figure also shows data on use of other facility services and MCP. Claims for these services are submitted for 95% of patients. Just over 80% of patient months involve claims for other facility services—which also means that nearly one out of five patients months does not. MCP payments are made in 95% of patients months. The reasons that MCP payments were not made in one out of 20 patients months has not yet been explored.
- **Note that these figures are based on patient months in 2003 for hemodialysis patients only. They include all patient months with between 1 and 20 sessions, whether or not any 'events' occurred to disrupt a 'full month' of dialysis.**



- A starting point for an analysis of bundling is the pattern of dialysis across patient months. The month is the basic “unit” for which providers — both dialysis facilities and other suppliers/providers — bill for the services they provide. From a clinical perspective the month is a somewhat arbitrary or artificial unit. Clinically, the week or even the session may be a more meaningful unit for some analyses. Unfortunately, the claims data that must be used to support analysis are monthly.
- Patient months can be classified according the kind of ‘events’ that occur within them: initiation of dialysis, training, transplant, death/termination of dialysis, hospitalization, a change in modality, transfer between facilities, multiple events, and an ‘other’ category that includes months with unexpectedly low number of sessions without any obvious cause. The ‘base’ or ‘reference’ case is a ‘full’ month of dialysis without any other ‘events’.
 - 73% of all months are ‘full months’ involving no other ‘events’.
 - 15% of all months involve a hospital stay.
 - 6% of all months involve an ‘unexplained’ low number of dialysis sessions.
 - 3% of all months involve a transfer of a patient between facilities.
 - Just over one percent (1.3%) of all months involve termination of dialysis.
 - Each of the remaining categories each account for less than 1% of months.
- The frequency of dialysis varies substantially across these different types of months. On average, patients experiencing a ‘full month’ of dialysis and no other events use 13 sessions. Patients starting dialysis, undergoing transplant, or terminating dialysis use less than half that number of sessions. Patients experiencing a hospital stay or multiple events (which may include a hospital stay) or with an unexpectedly low number of sessions, use between 9 and 10 sessions (on average).



- This figure (and the figures that follow) expresses the average number of sessions per month as a ratio. This approach is used to permit a more direct comparison of per session and per month statistics in subsequent slides. The raw data are presented in the accompanying data tables. The figure displays the ratio of: (1) the average value of the variable for a given type of month to (2) the average value of the variable for 'full months'. Thus, the 'full month' has a value of 1.0. Months in which dialysis starts have a value of about 0.4, which means that, on average, patients starting dialysis use only 40% as many sessions as patients receiving a 'full month' of dialysis.
- In general, it appears that four broad patterns of dialysis frequency can be distinguished.
 - Routine / full-month without 'events'
 - Months involving a hospital stay
 - Start-up months
 - Termination months (transplant/death/withdrawal)
- Months broadly similar to 'full-month'
 - Training months (slightly above average)
 - Change in modality (slightly below average)
 - Transfer between facilities
- Months broadly similar to 'hospital' months
 - Multiple events (which may include a hospital stay)
 - 'Unexplained' low number of sessions



- Not surprisingly, monthly payments under the composite rate vary directly with the number of sessions provided to the patient during the month.
- The average payment per session for composite rate services is about 10% higher than the average in a “full month” during which no “events” occur only in:
 - Months that involve training or
 - Months that involve a change in dialysis modality.
- The average monthly payment for composite rate services is lower than the “full month” average in those months in which the number of sessions is lower. These include:
 - A month in which dialysis starts, a transplant occurs, or the patient dies or otherwise discontinues dialysis (between 50% and 60% below the ‘full month’ average).
 - A month in which a hospitalization occurs, multiple events occur, or the number of sessions is inexplicably low (between 20% and 30% below the ‘full month’ average).
- Per month composite rate payment are above the ‘full month’ average in training months by nearly 20%.
- These patterns have no bearing on the question of what should be included in the bundle. The bundle must include the composite rate services.
- These patterns may have implications for *how* a bundled payment system might work. These data appear to lend support for a session-based payment system. However, it should be kept in mind that the lack of variation in the composite rate payments is itself largely an artifact of the current payment system.

Bundle 1A: Selected Drugs / Labs

- Included drugs
 - EPO
 - Iron
 - 'Vitamin D'
- Included labs
 - 'Anemia' laboratory tests
 - 'Vitamin D' laboratory tests

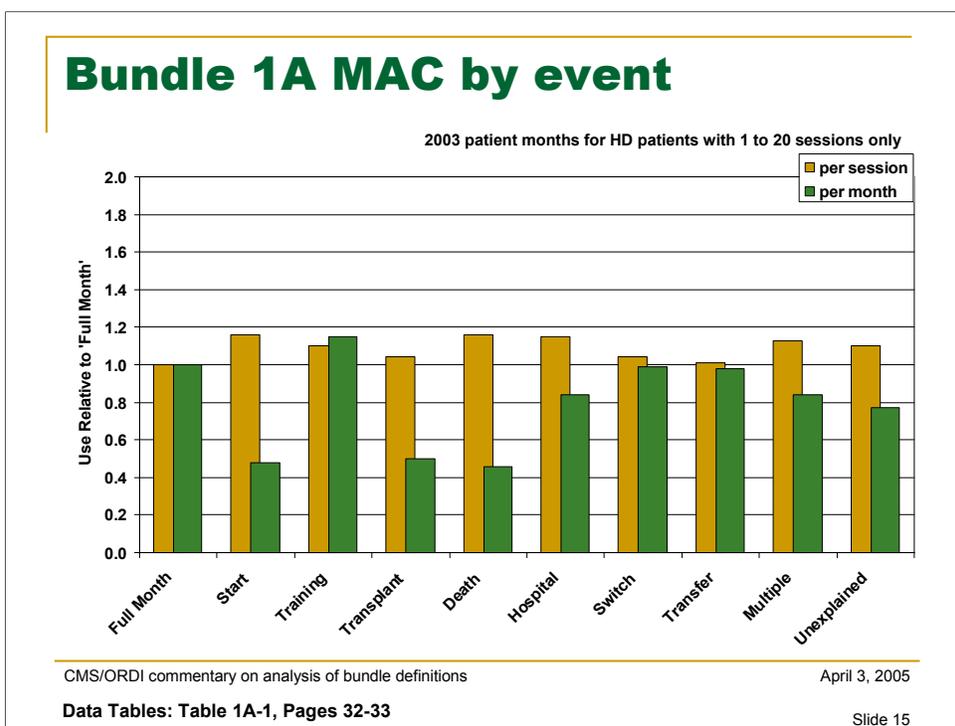
CMS/ORDI commentary on analysis of bundle definitions

April 3, 2005

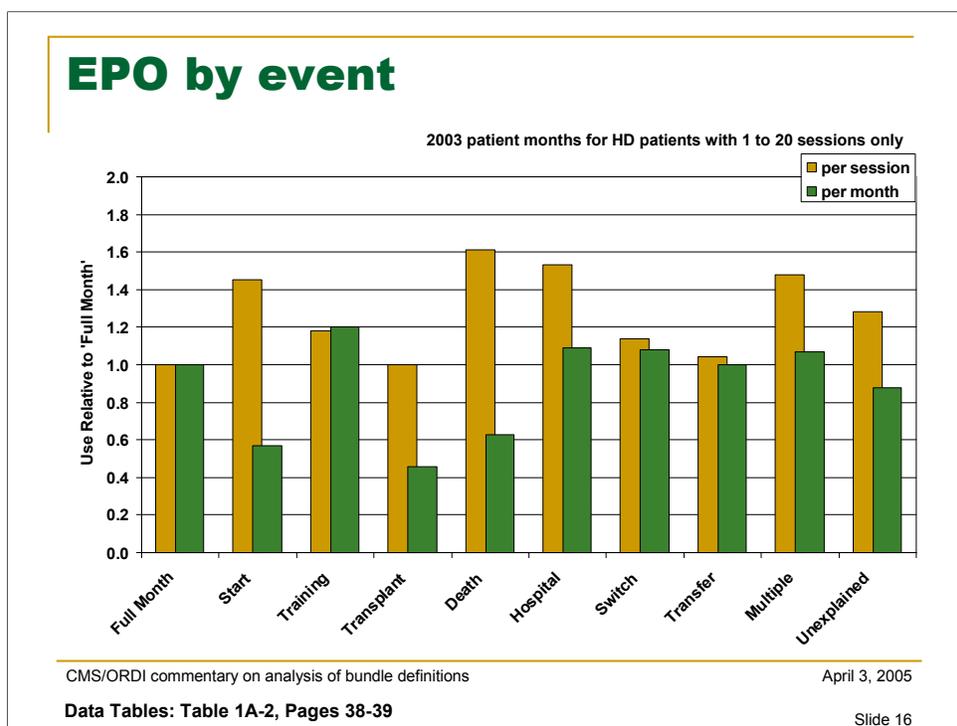
Data Tables: Definitions, Pages 3 (drugs) and 4 (labs)

Slide 14

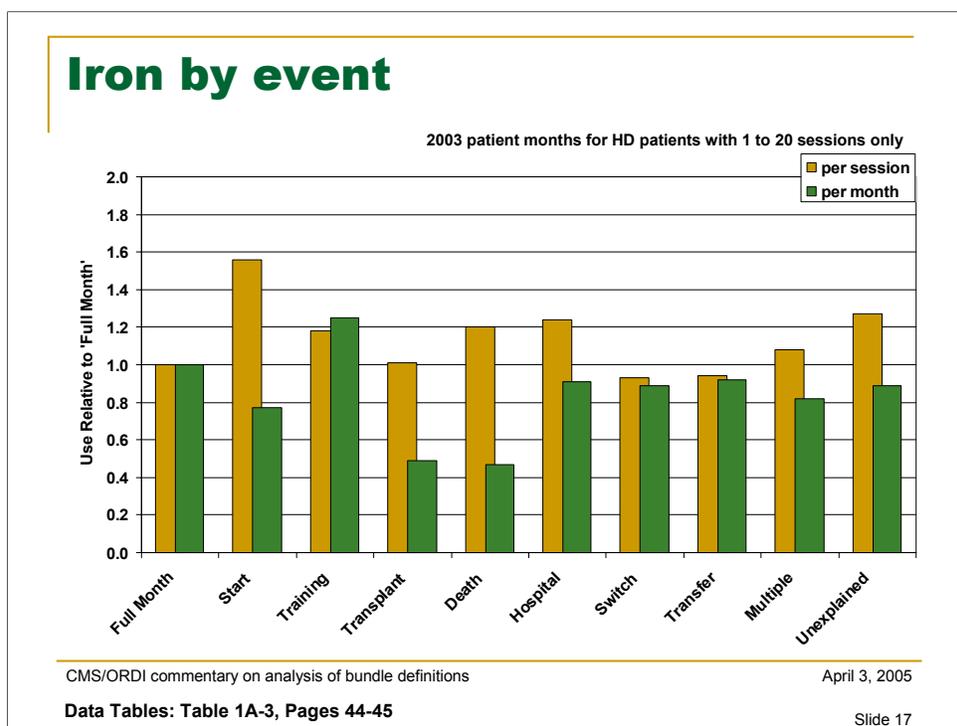
- Bundle 1A consists of composite rate services plus selected drugs and related laboratory tests.
- The selected drugs include:
 - EPO and Aranesp
 - Iron
 - 'Vitamin D'
- The selected laboratory tests (numbering about 36) have been grouped into two broad categories.
 - Tests related to the management of anemia (~25 tests/HCPCS codes)
 - Tests related to management of 'vitamin D' (~9 tests/HCPCS codes)
- The specific tests included in each group are listed on page 4 of the data table document.



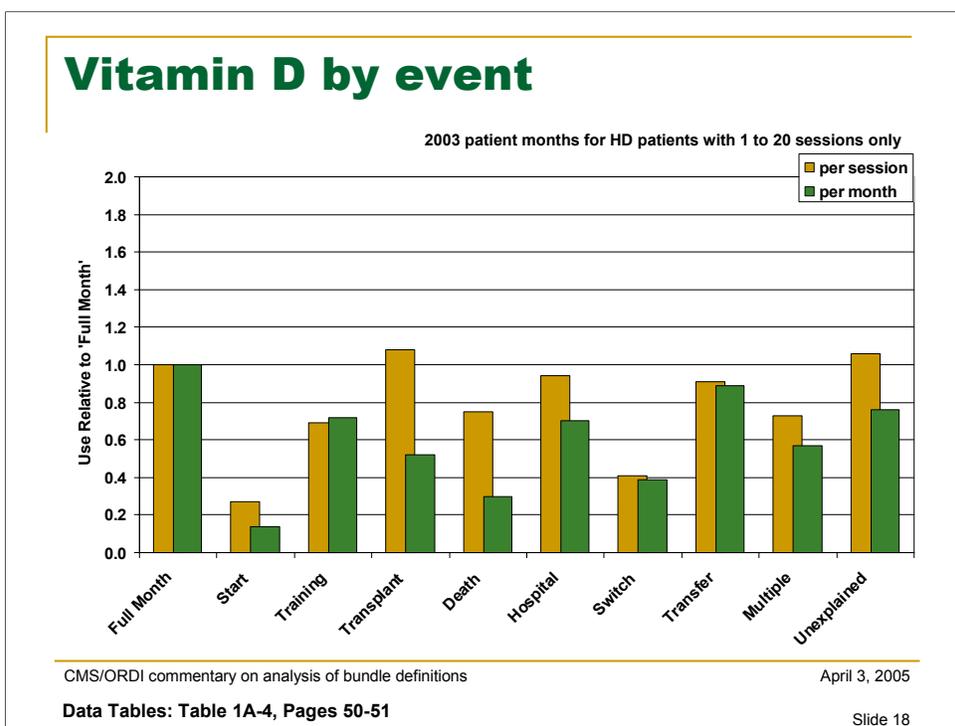
- Overall and unsurprisingly, Medicare 'payment' (maximum allowable costs/charges) displays a pattern that is broadly similar to the pattern of dialysis frequency.
- A 'full month' without other events has an average payment of \$2,828 per month or \$217 per session. This is the reference case.
- The average payment per session is broadly similar across all types of months, but ranges up to almost 20% above that for a 'full month' of dialysis.
- The average payment per month displays substantial variation across types of months.
 - Months that involve a *change in modality* or *transfer* between facilities have average payments that similar to a 'full month' of dialysis.
 - Months involving the start of dialysis, transplant, or termination of dialysis have average payments that are less than half that of a 'full month'.
 - Months that involve a hospital stay, multiple events, or unexplained low frequency of dialysis, have average payments that are about 20% below that of a 'full month'.
 - Months involving training have average payments that is 16 percent above that of a 'full month'.
- The variation in per month payments is generally, but not strongly, inverse to variation in per session payments. That is, months in which the frequency of dialysis is low have lower per month costs, but also have higher per session costs relative to those of a 'full month'. This pattern becomes more complex when composite rate services are distinguished from separately billable services.



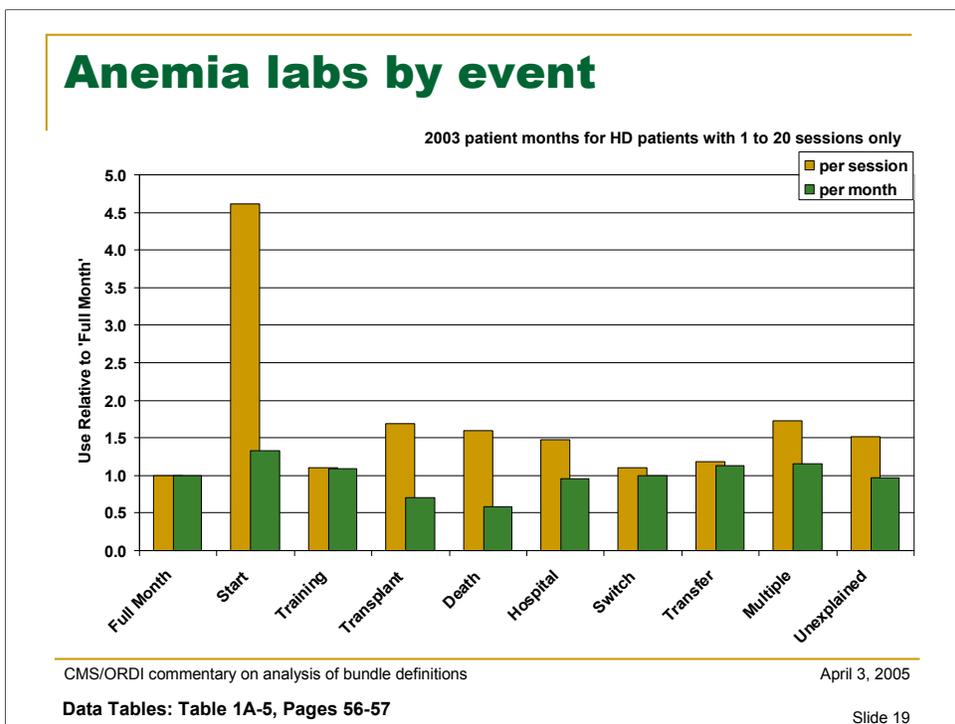
- EPO / Aranesp (EPO for short) payments are much less strongly correlated with the number of sessions provided during a month. Composite rate payments show little variation across types of patient months on a per session basis, but show considerable variation on a per month basis. In contrast, EPO shows considerable variation across types of patient months whether viewed on a per session basis or on a per month basis.
- Monthly EPO payments *are* higher in months in which sessions are more frequent, but not proportionately.
- *Monthly* payments for EPO are substantially lower in the initial months, terminal months, and the transplant months. In both the initial and terminal month, *per session* payments for EPO are also substantially higher (40% to 60%) than in 'full months' in which no events occur.
- *Monthly* payments for EPO are just slightly above payment in 'full months' for those months that involves hospitalization, transfer to another facility, a change in modality, or multiple events (including hospitalization). Because fewer sessions are billed in months involving hospitalization, *per session* payments for EPO are sharply higher in months with a hospital stay or multiple events (which often include a hospital stay).
- In 'training' months, EPO payments on both a per session and per month basis are about 20% above payments in 'full months' during which no events occur. The higher monthly payment appears to be related to a higher per session EPO payment, not more frequent dialysis in these months.
- These patterns have significant implications for how a bundled payment that includes EPO would need to work. Whether paid for on a per session or per month basis, payment for EPO will require robust adjustments to address potential under- or over-payment. The substantial variation in EPO payments on both a per session and per month basis *within* any type of month further suggests the need for robust case mix adjustments *to address potential under- or over-payment at the level of the patient if not the facility.*



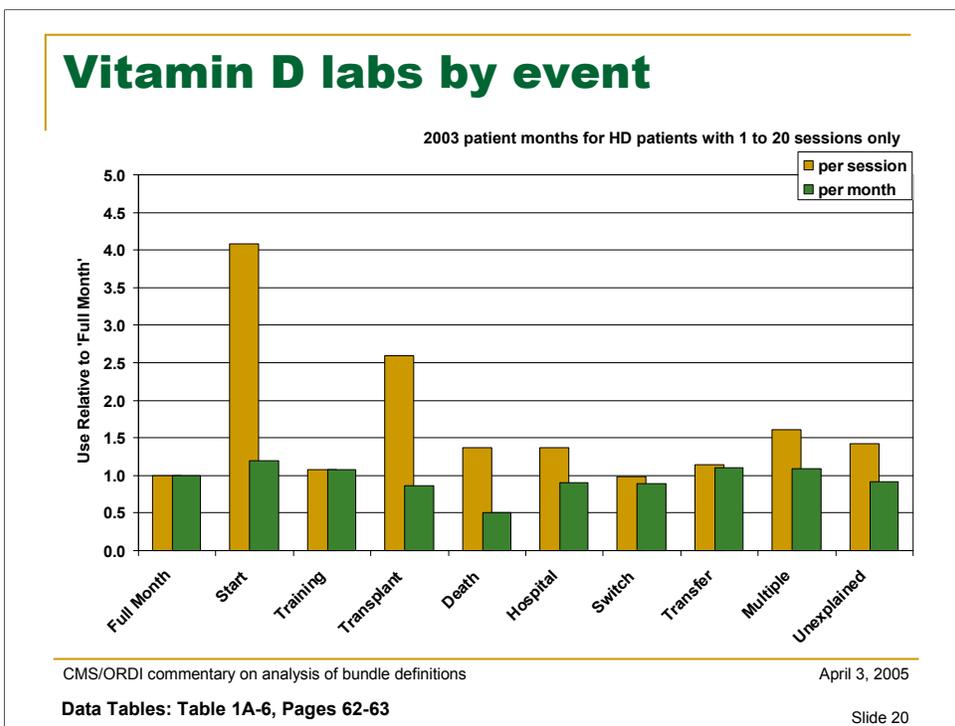
- Payment for iron follows the same *general* pattern as payment for EPO. However, the pattern is somewhat varied and complex. A higher percentage of patient months involve no payments for iron than for EPO and the variability in iron payments is larger within types of patient months and within facility types.
 - Use of iron *per month* is substantially lower in months involving transplant or termination of dialysis. It is about 20% below that of a 'full month' in the initial month and in months involving multiple events (including hospitalization).
 - Use of iron *per session* is substantially (~60%) higher in the initial month of dialysis. It is between 20% and 25% higher than in a 'full month' in training months, terminal months, months involving a hospital stay, or months in which frequency of dialysis is inexplicably low.
- The variability of iron usage is greater than EPO and much greater than use of composite rate services.
 - More than 25% of all patient months of any type involve no payments for iron. More than half of all initial months, transplant months, and terminal months involve no use of iron.
 - Consistent with this skewed distribution, the median use of iron is generally less than half the mean use of iron. In contrast, the median use of EPO was more than 70% of the mean use of EPO.
- These patterns have several implications consistent with EPO. Payment for iron will require robust adjustments to address potential under- or over-payment. The variation in iron payments *within* any type of month further suggests the need for robust case mix adjustments *to address potential under- or over-payment at the level of the patient if not the facility*. However these adjustments may differ from those needed for EPO.



- Payments for 'vitamin D' show a still more complex and varied pattern. As with EPO and iron, average monthly payments for 'vitamin D' are generally higher in those types of months that involve more frequent dialysis. However, 'vitamin D' payments do not appear to vary in proportion with sessions.
- 'Vitamin D' payments show substantially greater variability than EPO or iron within types of months or with types of facilities.
- These patterns also suggest that a naïve bundling of 'vitamin D' into a per session payment (i.e., of a fixed amount) will run into difficulties. As with EPO and iron, robust adjustments may be needed to prevent under- or over-payment for 'vitamin D' as a result of events that affect the frequency of dialysis.



- Compared to the dollar amount associated with EPO and Iron, the dollar amounts associated with laboratory tests thought to be related to anemia seem tiny. Payments for anemia lab tests average \$28 *per month* and \$2.51 *per session* for all hemodialysis patients.
- Payments on a per month basis range from just above 50% of the 'full month' payment in terminal months of dialysis to 133% above that of the 'full month' in the initial month of dialysis.
- In months involving a transplant, payments are *below* that of a 'full month' on a *per month* basis, but are *above* the *per session* payment for a 'full month'.
- In months involving a hospital stay, the *per month* payment is about equal to that of a 'full month', but is nearly 50% higher than a 'full month' on a *per session* basis.
- A potentially significant characteristic of these 'anemia' labs appears to be fairly standard patterns of utilization. The 25th, 50th and 75th percentiles display little variation across types of patients or even providers.



- 'Vitamin D' labs appear to follow a pattern similar to that of anemia labs, although use of these labs appears to be concentrated in a smaller percentage of patient months. Payments for 'vitamin D' labs are, therefore, somewhat more variable than payments for the 'anemia' labs.
- As with the 'anemia' labs, there appear to be fairly standard patterns of utilization. The 25th, 50th and 75th percentiles display little variation across types of patients or even providers.

Bundle 1B: 'Major' Drugs / Labs

- Included drugs (beyond bundle 1A)
 - Levocarnitine
 - Alteplase
 - Vancomycin
- Included lab tests (beyond bundle 1A)
 - 'Infection' laboratory tests
 - 'Carnitine' laboratory tests

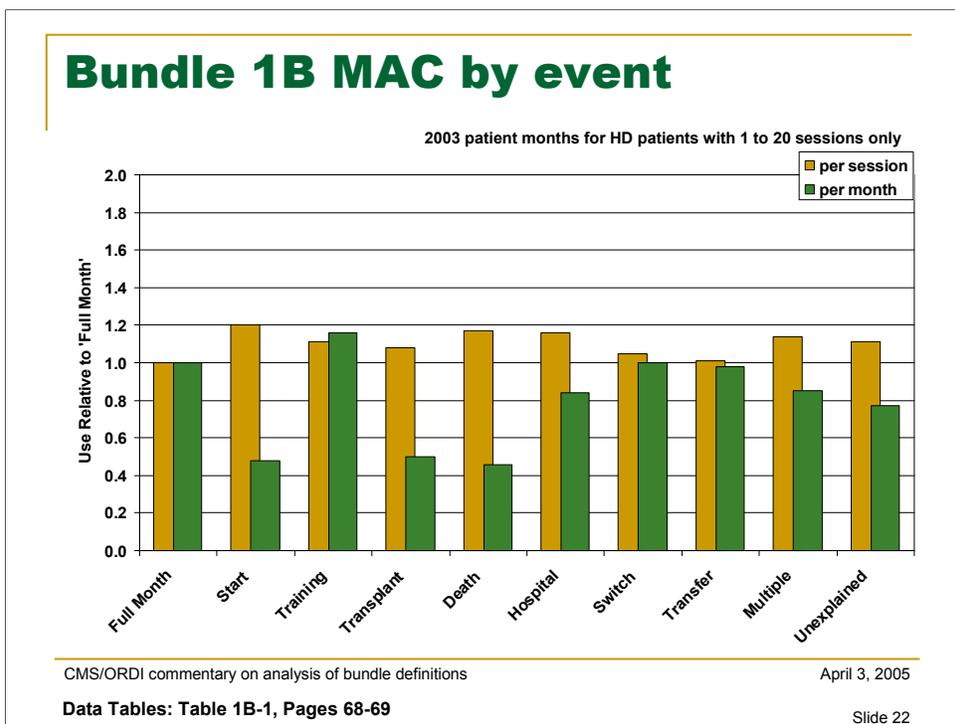
CMS/ORDI commentary on analysis of bundle definitions

April 3, 2005

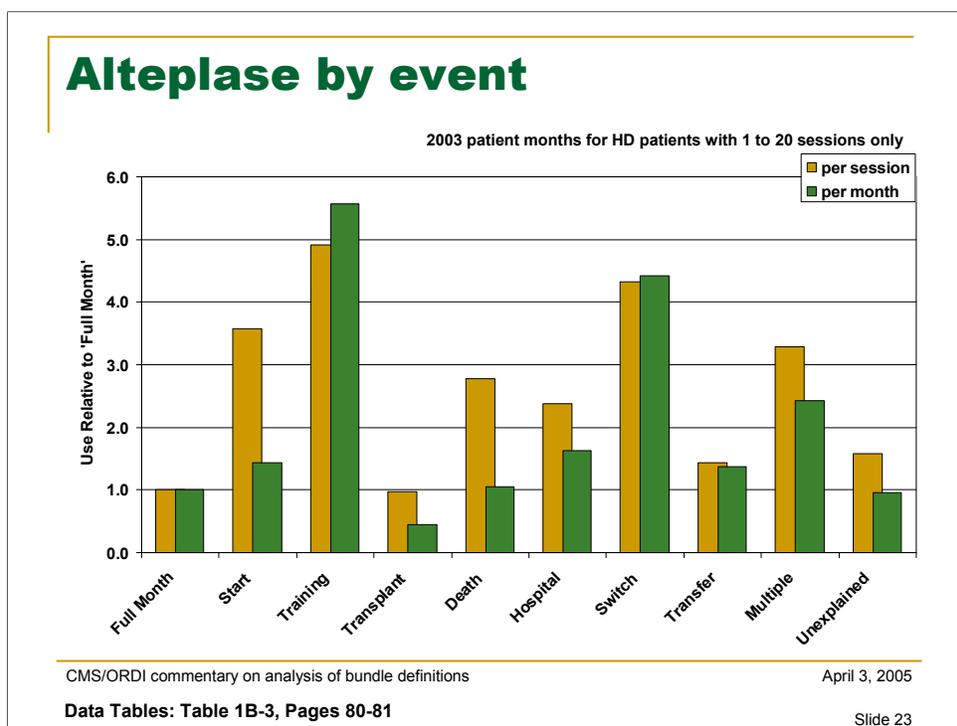
Data Tables: Definitions, Pages 3 (drugs) and 4-5 (labs)

Slide 21

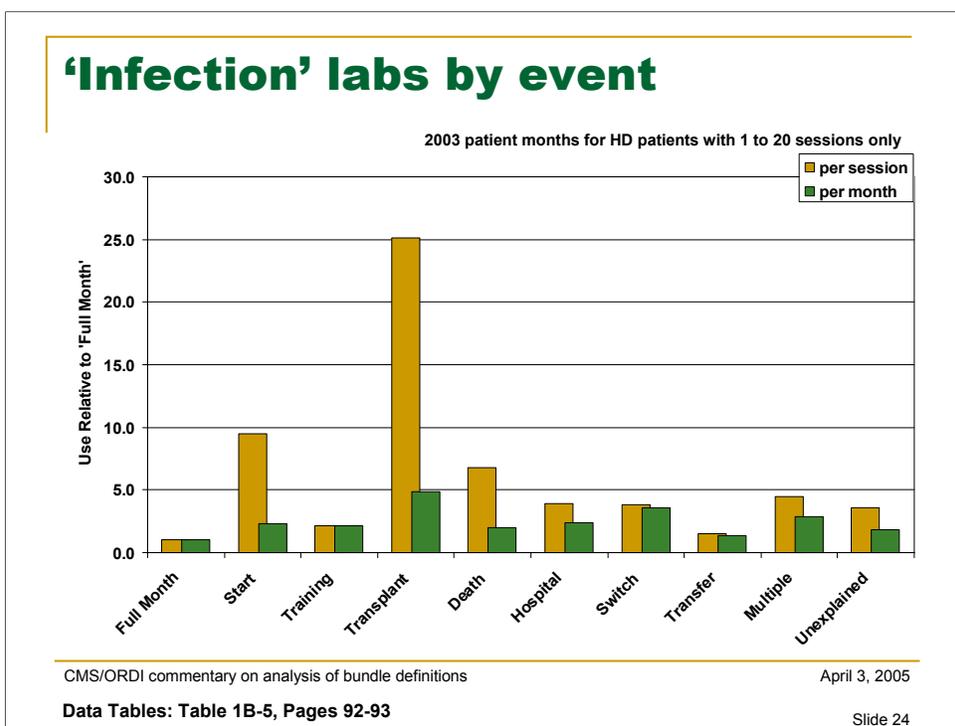
- Bundle 1B consists of composite rate services, plus the Bundle 1A drugs and laboratory tests, plus other 'major' drugs and related laboratory tests related to ESRD. These additional drugs were identified and have been the focus of attention by the Office of Inspector General of the Department of Health and Human Services.
- The 'major' drugs that are added to Bundle 1B include:
 - Levocarnitine
 - Alteplase
 - Vancomycin
- The selected laboratory tests (numbering about 34) have been grouped into two broad categories.
 - Tests related to the management of infection (~24 tests/HCPCS codes)
 - Tests related to management of carnitine (~10 tests/HCPCS codes)
- The specific tests included in each group are listed on pages 4-5 of the data table document.



- The increment in total payment associated with the additional drugs and related laboratory tests included in bundle 1B is just \$29 per month.
- Given the relatively small dollar value associated these drugs and related tests, it isn't surprising that the overall patterns of a 'bundled' payment across different types of months is generally unchanged.
- This similarity in the aggregate picture, however, conceals some distinctively different patterns at the level of individual components of this bundle.



- Alteplase adds just over \$7 to per month payments, however there are wide variations across types of patient months. It also displays considerable variation across types of patients.
- Use of alteplase is substantially higher than in a months in which no 'events' occur in:
 - Training months
 - Months in which a patient changes dialysis modalities
 - Months in which multiple events occur
- Use of alteplase is lower in months in which a transplant occurs.
- The differences in the pattern of variation across types of months between *per session* and *per month* payments indicates that a simple add-on may be problematic without robust case mix or other adjustments.
 - The possibility that case mix methods may be able to address this issue is suggested by the fact that use appears to be strongly associated with age. On a per month basis, alteplase payments are more than \$30 for patients under age 17, compared to an average of \$7.65 for all hemodialysis patients. Use is also slightly higher for patients over age 85.
 - The data on age variation is found on pages 78 and 79 of the data table document.



- Laboratory tests for 'infections' add just over \$6 to per month payments, however there are wide variations across types of patient months.
- Months in which 'events' occur all have higher average payments for laboratory work related to 'infections'. This should probably not be surprising as a leading cause—or consequence—of the 'events' which interrupt regular dialysis is probably infection.
- Compared to a 'full month' of dialysis, average *per session* payments for infection laboratory tests are:
 - Nearly ten times higher in the initial month of dialysis
 - More than twice as high in a training month
 - More than 25 times higher in a transplant month
 - From about 4 to 8 times higher in months involving termination of dialysis, a hospital stay, a change in modality, and multiple or unexplained events.
- In terms of monthly payments for laboratory tests, these differences translate into additional payments that range from \$6.30 (months involving a transfer between facilities) to \$22.62 (months involving a transplant).
- It may be easy to overstate the implications of these variations for bundling these laboratory tests into the payment system given the modest dollar amounts involved. However, these patterns do suggest the need for distinctive case mix or other adjustments.

Bundle 1C: 'All' Drugs / Labs

- | | |
|---|--|
| <ul style="list-style-type: none"> ■ Included drugs: <ul style="list-style-type: none"> □ Hepatitis B vaccine □ Flu vaccine □ Cefazolin □ Ceftriaxone □ Cefazidime □ Heparin sodium □ Filgrastim | <ul style="list-style-type: none"> ■ Included labs <ul style="list-style-type: none"> □ All tests billed by 10 largest 'freestanding' labs □ ~285 tests/HCPCS codes in addition to those included in bundles 1A and 1B |
|---|--|

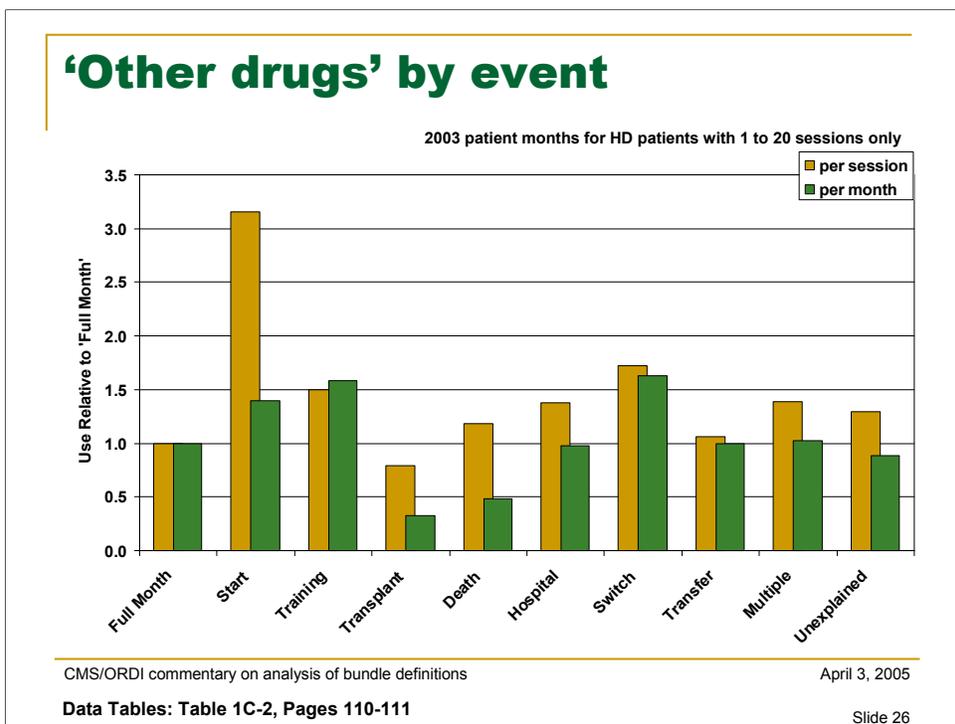
CMS/ORDI commentary on analysis of bundle definitions

April 3, 2005

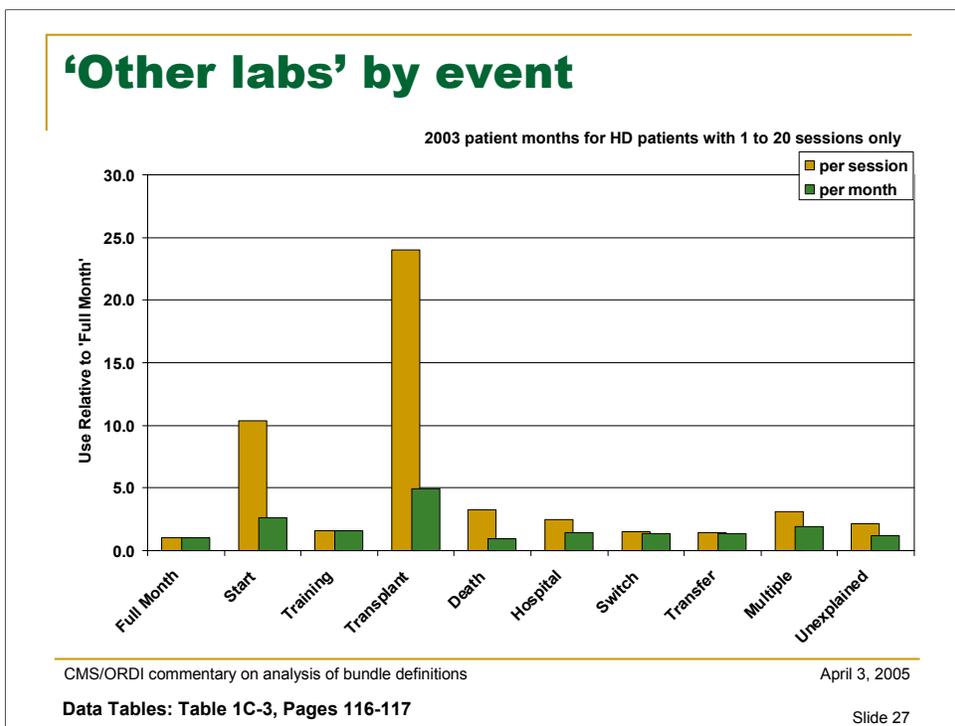
Data Tables: Definitions, Pages 1 (drugs) and 5-12 (labs)

Slide 25

- Bundle 1C consists of composite rate services, plus the Bundle 1A drugs and laboratory tests, plus the Bundle 1B drugs and tests, plus most other drugs and laboratory tests performed for ESRD patients.
- The 'drugs' that are added in Bundle 1C include:
 - Hepatitis B vaccine
 - Flu vaccine
 - Cefazolin
 - Ceftriaxone
 - Cefazidime
 - Heparin sodium
 - Filgrastim
- Note: It is not clear whether these exhaust the drugs billed by dialysis facilities. It will also be necessary to examine the extent to which implementation of Medicare Part D will affect the provision of these (or other drugs) by dialysis facilities.
- The laboratory tests that are added in Bundle 1C include all tests billed by the 10 largest 'freestanding' laboratories (including the laboratories owned/affiliated with large dialysis chains) for dialysis patients.
 - The tests included number ~285 tests/HCPCS codes
 - The specific tests included in each group are listed on pages 5-12 of the data table document.



- The seven ‘other drugs’ included in bundle 1C contribute just over \$10 to the average payment per patient month.
- Payments for these drugs is substantially above that of the average ‘full month’ of dialysis in the initial month of dialysis, training months, and months in which a patient changes modalities. In these months the per session payment exceeds that of a ‘full month’ by 300%, 50%, 70%, respectively.
- It is substantially below average (at least on a monthly basis) in months in which a patient receives a transplant or terminates dialysis. However, in these months, per session payments for these drugs is closer to the average for a ‘full month’. Nevertheless, in transplant months the per session payment is still 20% below that of a ‘full month’, while in the terminal month of dialysis the per session payment is almost 20% above that of a ‘full month’.
- These payments are concentrated in only 14% of patient months. In those months in which payment for these drugs is made, the dollar amount is substantial. It exceeds \$100 in 5 percent of patient months.



- The 285 ‘other labs’ included in bundle 1C cover a very broad range of services. Together, they contribute just over \$35 to the average payment per patient month.
- In the initial month of dialysis, payments for these lab tests are more than 2.5 times payments in the average ‘full month’ of dialysis. Payments are nearly 5 times those during the average ‘full month’ in months in which a patient receives a transplant. On a per session basis, these differences are even more dramatic: 10 times (for initial months) and more than 24 times (for transplant months) the average per session payment during ‘full months’.
- While less dramatic, payments for these ‘other labs’ is substantially above the average of ‘full months’ for all other months in which ‘events’ occur. This is true on both a per session and per month basis.
- Not surprisingly given their large number and diverse mix, payments for these ‘other lab tests’ are common. They occur in 84 percent of patient months and for virtually all patients.

Bundle 1D: All Facility Services

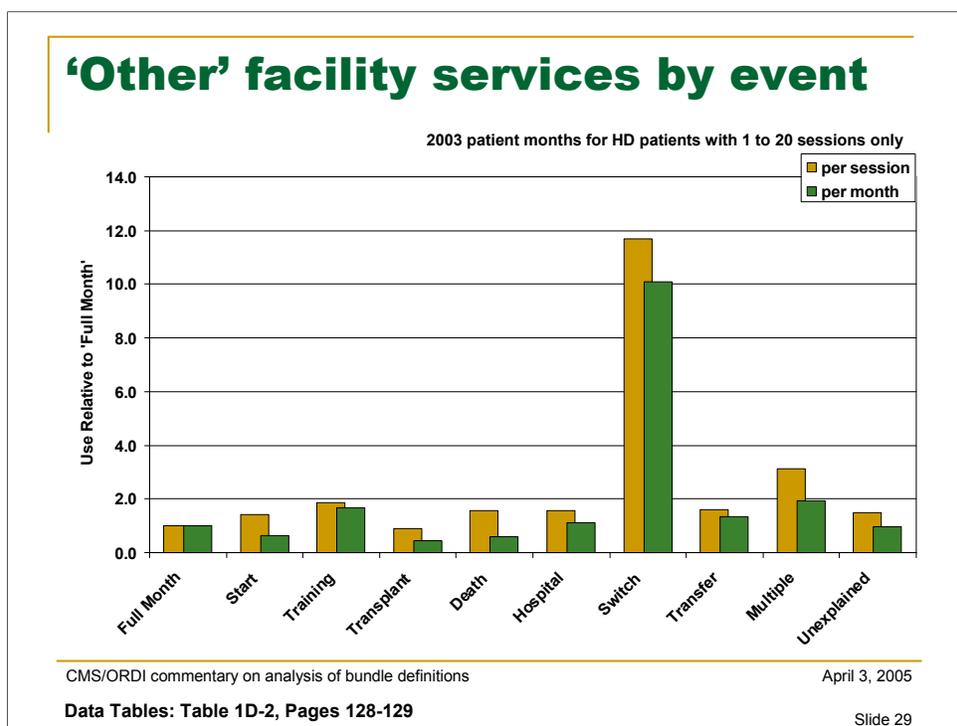
- Includes all services billed by dialysis facility
 - Medical / surgical supplies
 - Pharmacy services
 - Preventive services
 - Blood processing
 - Diagnostic services (e.g., EKG/ECG)
 - Imaging procedures
 - Etc.

CMS/ORDI commentary on analysis of bundle definitions

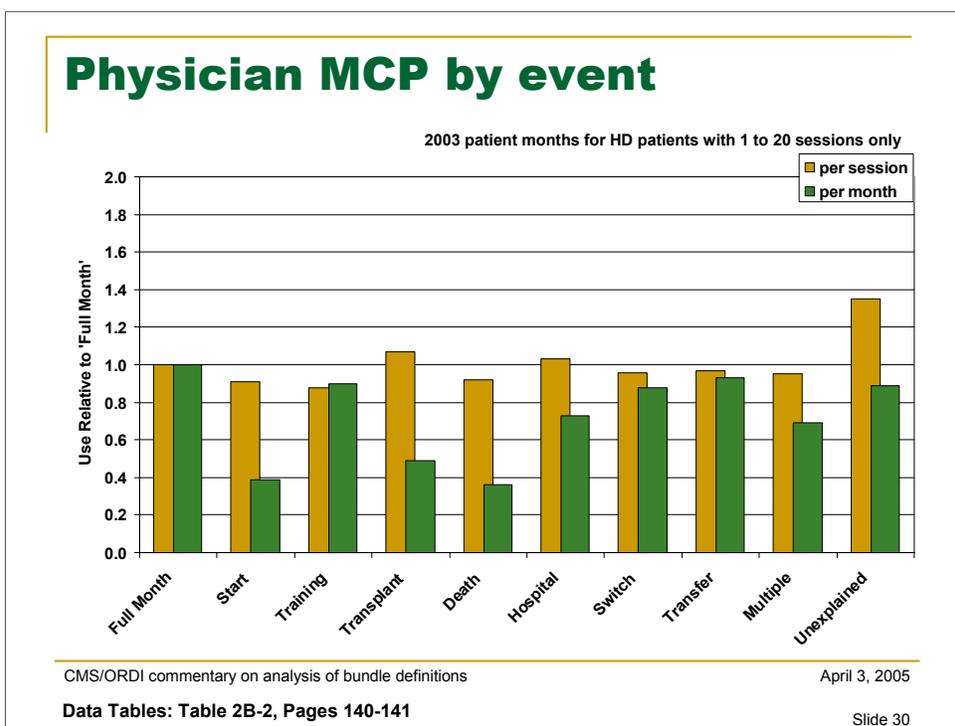
April 3, 2005

Slide 28

- Bundle 1D adds to the previous bundle all services that dialysis facilities presently bill for that have not already been included in a previous bundle.
- These services cover a broad range of services and supplies:
 - Medical / surgical supplies is the largest, accounting for \$19 million
 - Pharmacy (presumably other than the drugs already captured in bundles 1A-1C) accounts for \$6.1 million
 - Preventive services account for \$915,000
 - Blood processing / storage accounts for \$3.4 million, and blood products for another \$612,000
 - Diagnostic services such as ECG/EKG account for nearly \$600,000
 - Imaging accounts for \$178,000
- While collectively the dollar figures seem to be non-trivial, they also amount to less than one percent of composite rate payments and account for less than 1.5% of total 'incremental billing'.



- ‘Other facility services’ display a very different pattern from other types of payment. The type of month associated with the highest ‘other facility’ payments are months involving a change of modality.
- In a month involving a modality switch:
 - Payments *per month* are more than 10 times those in a ‘full month’. In dollar terms, the average payment is more than \$160 PPM compared to less than \$15 in an average ‘full month’.
 - Payments *per session* are nearly 12 times payments in a ‘full month’ in which no events occur. In dollar terms, the average per session payment is \$14.25 compared to \$1.22 in an average ‘full month’.
- ‘Other facility services’ payments are substantially higher in hospital-based than in freestanding chain or non-chain dialysis facilities. They are also substantially more concentrated in a small number of patients in hospital-based facilities.
 - The average payment per patient month in hospital-based facilities for ‘other facility services’ is more than \$40, and payments for these services involve fewer than 50% of all patient months.
 - In the average freestanding chain facility, the payment averages \$12, and payments involve more than 75% of all patient months.
 - This pattern may be an artifact of the way patient months are ‘attributed’ to types of facilities in this analysis. However, it is also possible that they reflect differences in patterns of referral, care, and billing across different types of facilities.



- Note:** the MCP that is the basis for this figure and the data shown in the associated tables reflects payment policies that were changed substantially in 2004. These payments do not use the new “G” codes and so may, or may not, reflect current patterns of payment.
- The physician Medicare Capitation Payment (MCP) follows the same general pattern as composite rate payments. It generally varies proportionately with the number of dialysis sessions, though with some exceptions. For example, training months involve more sessions than an average ‘full month’ of dialysis, but the MCP is lower in training months.
- Like composite rate payments, *per session* MCP is close to the average for all types of months. Setting aside the months with an ‘unexplained’ low number of sessions, the average MCP ranges from 12% below the ‘full month’ in ‘training’ months to 8 percent above the ‘full month’ average in months involving a transplant.
- Like composite rate payments, the MCP shows little variation across types of patients or facilities. Within categories of patients or facilities it fluctuates in a very narrow range.
- The data on the MCP are found in the data table document on pages 138 to 143.

The Law of Averages and the Law of Unintended Consequences

- The law of averages
 - Differences at the patient level average out
 - Facility averages can mute patient-level variation
 - The law of large numbers
- The law of unintended consequences
 - Patient-level differences and payment equity
 - Patient-level differences and patient 'selection'
 - The need for robust adjustments
 - Case mix adjustments: address patient characteristics
 - Payment adjustments: address what case mix can't

CMS/ORDI commentary on analysis of bundle definitions

April 3, 2005

Slide 31

- Throughout this discussion, attention has focused on differences or variations that are apparent at the level of the individual patient. Ideally, a payment system would accurately reflect these patient-level differences. Of course, prospective payment systems don't ever deliver the precisely correct amount of money needed to pay for each patient's care.
- Prospective payment systems rely on the **Law of Averages** to compensate for their inability to precisely match payment to patient needs. A provider may "lose" or "make" money on an individual patient, but the differences tend to cancel one another out. The "profit" earned on some patients is used to offset the "losses" incurred on other patients. In a sense, differences at the patient level are muted in the facility average. Differences in facility-level averages may be more revealing of the limitations of a payment system than differences among individual patients (or in the present case patient months). For this to be true, however, it is necessary to have fairly substantial numbers of patients over which to average costs and payments.
- A corollary of the Law of Averages is the **Law of Unintended Consequences**. The tendency of gains and losses at the individual patient level to cancel each other out at the level of the facility does not eliminate the need to be concerned about patient-level differences. To the extent that facilities systematically draw "high cost" patients, payment inequities arise with potentially significant consequences for access to care and quality. And to the extent that a provider can influence the mix of patients that it cares for, patient-level differences create an opportunity to profit from patient selection instead of (or in addition to) efficiency.
- The size and nature of the differences in patient-level needs is therefore important as an indication of the need for : (1) robust case mix adjustments to better match patient needs and payment; and (2) other payment adjustments to address variation that case mix should but cannot capture. Or vice versa.