Overview:

The need for this project arose because the Texas Medicare Administrative Contractor (MAC), Trailblazer Health Enterprises, Inc., began to deny payment for chemotherapy and other services based on a very restrictive view of medical necessity. In many cases, our cancer experts did not agree with this restrictive interpretation. In fact, in several examples, Trailblazers’ position was inconsistent with the authoritative peer-reviewed literature. As a result, MD Anderson experienced material financial losses as demonstrated in graph one:

Because of the significant issue found with drugs, the project began with a focus on this service. Had coverage restrictions continued, without intervention, the write-offs were anticipated to continue to rise to an unsustainable point. (See graph two.)
To ensure success, we assembled a multi-disciplinary team of 13 support departments (Revenue Cycle plus key clinical operational departments) and the 26 outpatient clinical areas. The project aligns with the MD Anderson Vision Strategy 1.4 – “We will collaborate with health care providers in our community, our country and throughout the world to deliver optimal cancer care to our patients and make use of enhanced information-sharing technologies.”

The actual project work took place in a series of multidisciplinary planning sessions with “homework” occurring within the involved departments.

**Aim Statement:**

The project’s aim was to ensure that clinically appropriate treatments are available to patients while reducing 2008 financial write-offs by at least 20% for treatments not covered by Medicare.

**Measures of Success:**

The project’s success was to be measured by 1) a decline in write-offs of at least 20% in the first year, and 2) by managing to sustain these results in the forward years.

**Use of Quality Tools:**

The project team employed a variety of quality tools, including:

![Baseline Data: Prediction of Drug Write-offs if left unchecked](image)
• Team Brainstorming,
• Meetings with Government Officials,
• a Project Charter,
• Multiple Process Flowcharts,
• Comprehensive Policy Development,
• Relations Diagram,
• Multiple Legal Analyses,
• Check Sheets,
• Benchmarking of Trailblazer policies with other states’ policies,
• A Radar Chart with other cancer centers (Alliance for Dedicated Cancer Centers),
• Plan Do Act Check methodology,
• Mistake Proofing,
• Multiplies presentations and trainings,
• Multiple Designs of Experiments,
• Multiple Graphs,
• Hypothesis Testing,
• a Pareto Chart,
• Sampling,
• Decision Trees,
• and Patient Brochures.

Lastly, our team employed an “if the clinician believes in the therapy we will NOT take “NO” for answer” motto when working with the MAC.

See exhibits one, two and three below for examples of the helpful quality techniques:

![Fish Bone Diagram](image.png)
Advanced Beneficiary Notice Workflow #1 with Swim Lanes
Interventions:

When designing our interventions, our team’s overall plan and commitment to the patients and our institution was:

1. The patient impact will be the **LAST RESORT**.
2. The program must be as seamless as possible to our clinicians.
3. Compliance with all federal regulations is a non-negotiable requirement.

Keeping this commitment at the forefront, we designed a hierarchy of interventions and implemented the strategy beginning with the drugs that had the greatest potential to make a positive financial impact.

1. Intervention #1 - Expand Coverage

   Tireless external advocacy was performed, including meetings with government officials, development of the National Comprehensive Cancer Network (NCCN) compendia, and litigation, when necessary. These efforts were supported by institutional top leadership as well as the Governmental Relations Department. These meetings began in early 2007 and have continued through 2011.
One important aspect of our meetings was demonstrating our review of coverage throughout the United States. When we compared the Texas coverage to coverage from other states, we were disappointed to discover that several chemotherapy drugs were available to patients in other regions of the country, but were not available to our patients. See map 1.

Map 1

Note: LCD stands for local coverage determination.

2. Intervention # 2 - Build Clinical Tools

Order sets were developed to assist clinicians in completing clear and thorough documentation of medical necessity. Order sets were particularly effective for supportive care drugs, for which documentation of medical necessity was the key issue. These efforts involved all 26 Outpatient Centers as well as numerous physicians. The designing of these order sets to accomplish clinical as well as financial goals was a particularly innovative and integrative approach for the project. Here is one example (Exhibit four):
3. Intervention # 3 - Educate physicians, coders, and patient access professionals.

Multiple training sessions regarding Trailblazers’ approach to medical necessity were provided to medical oncologists. Physicians were surprised and disappointed that excellent peer-reviewed articles and even FDA labeling did not guarantee coverage for certain drugs.

For example, upon comparing coverage for a certain 7 drug and diagnosis combinations, regional differences were highlighted. One example of a compelling/innovative way to explain this problem was the graph below, which was prepared for MD Anderson physicians (See Exhibit 5):
Lastly for intervention # 3, order sets were placed in unique folders for ease of locating for coding purposes. Coders were educated on clinical disease processes and documentation, where needed.

4. Intervention # 4 - Implement targeted advanced beneficiary notices.

Certain drugs were placed on a surveillance ‘watch’ list, which triggered additional monitoring by our financial analysts, and led to the implementation an advanced beneficiary notice process for “watch list” drugs. These efforts involved all 26 Outpatient Centers as well as a large contingent of physicians. We began with two drugs, performed “Plan, Do, Act, Check” functions, adjusted for lessons learned, then implemented an additional 3 drugs, then an additional 6, and a final 9 drugs. Now we are ‘current’ and able to implement any new drugs as coverage changes occur,” real time”.

Most importantly, the signed ABN enabled us to seek drug replenishment and/or to further pursue appeal of denials, including litigation where appropriate. Here is an example ABN form (Exhibit 6):
5. Intervention # 5 - Ask the patient to pay

Because of all of the interventions placed in operations prior to this intervention, (such as seeking Pharmacy Assistance for patients, expanding coverage with literature support) asking the patient to pay has truly been a rare event and has only occurred as the last resort. This fact, in and of itself, has been a great success of the project.

Results:

The project exceeded the first year expectation of a 20% reduction in write-offs by 9%, for a total reduction of 29%, (see graph 3).
The improvements continued and were sustained into years 2007-2011. (See graph 4.)

Sustaining Our Gain:
Prediction of Drug Write-offs if left unchecked
Revenue Enhancement /Cost Avoidance:

Once we had exhausted all reasonable external advocacy efforts, completed our education internally, and obtained drug replenishment wherever available, we embarked upon our litigation portion of the project to sustain the improvements and also to further provide support for the external advocacy efforts. The hypothesis was: if we can win in court on a few drug cases, perhaps then the MAC would be convinced (by being ordered to pay by a judge), to expand coverage for the drugs. Our hope was to avoid the litigation in the future but to make the drugs available as appropriate.

The litigation efforts have been wildly successful. See exhibits seven, eight, nine, and ten.

Level One
Individual Claim Appeals Progress
thru Dec 2011

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Exhibit 7
## Level Two

### Individual Claim Appeals Progress

*thru Dec 2011*

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## Level Three

### Individual Claim Appeals Progress

*thru Dec 2011*

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*Exhibit 8*

*Exhibit 9*
The total financial impact of this project has been far reaching. The drug write-offs avoided have exceeded $30 million for the period 2008-2011. Additionally, recoveries of drug write-offs due to appeal efforts exceeded $1 million for 2011 alone.

Furthermore, as a result of our determined resolve, many of the coverage expansion we were seeking have now been granted. These expansions have made these life-saving drugs available for all Medicare patients who need them throughout Texas, New Mexico, Oklahoma, and Colorado. Untold amounts attributable to other providers were another benefit of this project.

Conclusions and Next Steps:

In summary, this project has proved to have substantial value to patients, physicians, and to the cancer community.

For patients the project assisted in avoiding significant adverse financial consequences, reduced anxiety about financial matters, and, most importantly, helped patients to avoid having to choose suboptimal treatment choices due to financial reasons. To date, more than 175 of our patients have avoided paying over $6.9 Million for chemotherapy treatments due to successful Medicare appeals directly because of this project.

For physicians the project helped to enable medically appropriate treatments, and improved and streamlined medical documentation.
For the larger cancer community the same project benefits for patients and physician above also extended to them.

This project remains aligned well with our organizational goals of managing resources effectively and making important life-saving treatments available for all patients within our reach, including patients whom we do not treat at MD Anderson.

Our project continues; we have expanded our analysis to include diagnostic imaging services as well as other important treatment services for benefit of the cancer patient.

In late 2012 we are anticipating a transition to a new MAC from Pennsylvania. Our work with the new MAC, educating those officials on difficult issues, such as lack of peer reviewed literature for orphan cancers, etc. will continue.

We also anticipate additional work in this area for the subject of molecular pathology testing as well as intensity modulated radiation therapy.

We will continue our resolve to make a difference for all cancer patients who are counting us to remove obstacles to treatment. **Our resolve will remain great; patients are counting on us.**

Respectfully submitted,

Angela Simmons, CPA